IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

CENTOCOR, ET AL	*	Civil Docket No.
	*	2:07-CV-139
VS.	*	Marshall, Texas
	*	
	*	June 23, 2009
ABBOTT LABORATORIES	*	8:30 A.M.

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE JUDGE T. JOHN WARD
UNITED STATES DISTRICT JUDGE
AND A JURY

APPEARANCES:

FOR THE PLAINTIFFS:
MS. DIANNE ELDERKIN
MS. BARBARA MULLIN
MR. STEVEN MASLOWSKI
MS. ANGELA VERRECCHIO
MR. MATTHEW PEARSON
Woodcock Washburn
2929 Arch Street, 12th Floor
Cira Centre
Philadelphia, PA 19104

MR. RICHARD SAYLES
MR. MARK STRACHAN
Sayles Werbner
1201 Elm Street
4400 Renaissance Tower
Dallas, TX 75270

APPEARANCES CONTINUED ON NEXT PAGE:

COURT REPORTERS:
MS. SUSAN SIMMONS, CSR
MS. JUDITH WERLINGER, CSR
Official Court Reporters
100 East Houston, Suite 125
Marshall, TX 75670
903/935-3868

(Proceedings recorded by mechanical stenography, transcript produced on CAT system.)

APPEARANCES CONTINUED:

FOR THE DEFENDANTS: MR. WILLIAM LEE
MS. AMY WIGMORE
MR. WILLIAM MCELWAIN
Wilmer Cutler Pickering Hale and Dorr
1875 Pennsylvania Avenue, N.W.
Washington, DC 20006

MR. DAVID BECK
Beck Redden & Secrest
One Houston Center
1221 McKinney Street
Suite 4500
Houston, TX 77010

* * * * * *

P R O C E E D I N G S

COURT SECURITY OFFICER: All rise.

THE COURT: Please be seated.

Good morning, Ladies and Gentlemen of the Jury. Appreciate you being here timely.

Good morning, Counsel.

Who will be your next witness for the Plaintiff?

MS. ELDERKIN: Your Honor, may it please the Court. The Plaintiffs call Ken Dow.

COURTROOM DEPUTY: Raise your right hand,

please.

(Witness sworn.)

MS. ELDERKIN: Good morning, Ladies and Gentlemen of the Jury.

KENNETH DOW, PLAINTIFFS' WITNESS, SWORN

DIRECT EXAMINATION

BY MS. ELDERKIN:

Q. Mr. Dow, would you please introduce yourself to the jury.

A. My name is Kenneth Dow. I am a patent attorney with the Johnson & Johnson Law Department and Vice President of Patent Law for Centocor.

Q. So you are a patent lawyer?

A. Yes.

Q. Okay. You're familiar with the patent-in-suit, the '775 patent, correct?

A. Yes, I am.

Q. Okay. Who owns this patent?

A. It's co-owned by New York University and Centocor Ortho Biotech.

Q. And has that been the case since this lawsuit started?

A. Yes.

Q. Okay. And what rights, if any, did NYU, New York University, grant to Centocor under this patent?

A. Centocor has an exclusive license from New York University to their interest in the -- in the patent.

Q. Okay. I'd like to change gears a little bit. Have you ever been a party to a license negotiation with Abbott?

A. Yes.

Q. When did that happen?

A. Well, the first one was in 2002. We had a license negotiation where Abbott had approached us about getting a license under a patent that we had exclusive rights to from the Kennedy Institute of Rheumatology. And so we executed a non-exclusive license agreement with them for that -- those patent rights. And in return, we received a license under some patents that Abbott owned.

Q. And what were those patents?

A. Those were patents that related to anti-TNF antibodies.

Q. Do you recognize -- in your binder, there's a copy of Plaintiffs' Exhibit 669.

Do you recognize that exhibit?

A. Yes.

Q. And what is that?

A. This is the non-exclusive license agreement

from Abbott to Centocor relating to the TNF-alpha patents.

Q. Did Centocor ask for that license?

A. Yes.

Q. Why?

A. We were -- we had a product in development at the time, which was referred to as CNTO148, which later became Simponi. And at the time, it was in development, and we were aware -- when Abbott approached us about getting a license under the Kennedy patent, we were aware that Abbott had rights to these -- to these patents, and we were -- we knew that they were relevant at least to the -- to the TNF antibody field.

And we thought that we -- they had a whole family of patents on -- on file, and it was possible that one -- a patent might issue sometime that would cause a problem for us. So we decided to ask them for a license in return for the license that we gave them.

Q. Was it sort of an insurance policy in case you might ever need them?

A. Correct. It was just in case we needed a license in order to bring the product to the market, we would have the rights.

Q. Okay. Could you look at Exhibit 1.02 in that license agreement, please?

MS. ELDERKIN: And, Mr. Ficocello, if you could put that up on the screen.

I'm sorry. It's Exhibit 1.02. It's about three pages from the back.

THE WITNESS: Got it.

MS. ELDERKIN: There you go.

Q. (By Ms. Elderkin) Could you explain what this exhibit is? This is part of the license agreement, correct?

A. Right. This is a listing of all the patents that we received rights to. There's a whole family of patents here that were filed in different countries. And it also lists some U.S. patents; some that had issued and some that were still pending.

MS. ELDERKIN: Could you scroll down, please, Mr. Ficocello?

There you go.

Q. (By Ms. Elderkin) Are these the U.S. patents you're talking about?

A. Right.

Q. And some of them say pending?

A. Some of them were still pending.

Q. So what does that mean?

A. It means there were still applications that were on file in the Patent Office, and we didn't know at

the time what kind of claims they were going to get out of those patents. So we decided, as an insurance policy, we would take this license.

Q. So Abbott had filed an original application, but then filed a number of applications subsequent to that that related, and some of those were still pending?

A. Right.

Q. In 2002?

A. Right.

Q. Okay. Thank you.

Let's change gears one more time. Before this lawsuit was filed, did you have any discussions with John Conway at Abbott?

A. Yes. Well, before the lawsuit --

Q. Before the lawsuit, uh-huh.

A. -- was filed?

Yes. Shortly after Mr. Scodari notified Abbott that we had allowed claims in the '775 patent family, I received a call from John Conway, who was a patent attorney for Abbott.

And in the first phone call, we identified the patent, and then there was a second phone call shortly thereafter where he asked us whether we had any -- any data, any competition testing data that would support our claim.

Q. So competition testing for Humira, their product?

A. Right.

Q. And did you have such results?

A. Yes. I told him we had the results and that, in fact, it did compete with -- Humira did compete with Remicade for binding with TNF.

Q. Did you give him those results?

A. No. We -- when he asked me for the results, I said we would take it under consideration. And I went back to talk to my supervisors about it.

Q. Did you feel any pressing need to give them the results?

A. No. At the time, we were -- you know, we were in talks, and we had some discussions internally, but, you know, I -- we never really got back to them on it. And we figured that they would have -- they would do their own testing.

Q. Okay. And those test results, do you know if they have been produced to Abbott in this litigation?

A. Yes.

Q. Okay. Changing gears one more time, last time.

Did there come a time when Abbott sought an arbitration ruling on whether it had a license or

permission from Centocor under the patent-in-suit?

A. Yes.

Q. How did that happen and when?

A. Well, sometime after the lawsuit was filed, we received a letter from Abbott, indicating that they thought they already had a license to this -- to the '775 patent, and they requested arbitration on that issue.

Q. Okay. Would you look at Exhibit DX509 in your binder, please?

MS. ELDERKIN: And you can put that up, Mr. Ficocello, the first page.

Q. (By Ms. Elderkin) What is DX509?

A. This is the results of that arbitration. It's the award from the arbitrator.

Q. Okay.

MS. ELDERKIN: Let's look at the last page of this, Mr. Ficocello, under the heading, Award, and the numbered paragraph, 1, if we could highlight that.

Q. (By Ms. Elderkin) So what does this award say, Mr. Dow?

A. It says that Abbott does not have a license to take any action with respect to Humira that would constitute an infringement of the '775 patent, except

that with respect to Humira that qualifies as co-administration product under the license agreement, they would have a license.

Q. Okay. Just so the jury understands, did the arbitrator decide that Humira infringed?

A. No.

Q. Did the arbitrator decide that Centocor's patent was valid?

A. No.

Q. What was he saying here?

A. All he said was that to the extent there was infringement of the '775 patent, they did not have a license, except for this co-administration product.

Q. So they didn't have permission, if they needed it, except for that co-administration product?

A. That's right.

Q. And do you have an understanding as to what proportion of Abbott sales are co-administration product?

A. My understanding is that there was a second arbitration, and as a result of that arbitration, they determined that it was about one-third of Abbott sales that were licensed.

Q. And did they ever get permission for the rest of the sales?

A. No.

MS. ELDERKIN: Pass the witness, Your Honor.

THE COURT: Mr. Lee.

MR. LEE: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. LEE:

Q. Good morning, Mr. Dow.

A. Good morning, Mr. Lee.

Q. Just give us a minute, and we'll give you a notebook that will have the exhibits that I might ask you about, but you'll also see them on the screen.

A. Okay.

MR. LEE: If I can have a second, Your Honor.

THE COURT: Certainly.

COURTROOM DEPUTY: Sir, give me just a moment, and let me see if I can override.

THE TECHNICIAN: It's not moving.

THE COURT: I have a technician here that hopefully can solve the problem.

Steve, just go ahead and stay back there. We will call you if we need you, Steve. Thank you.

Proceed.

MR. LEE: Mr. Dow, you all set?

THE WITNESS: I'm ready.

MR. LEE: Okay. May I proceed, Your Honor?

THE COURT: Certainly. Please do.

Q. (By Mr. Lee) Mr. Dow, I want to start by asking you the questions I've asked every Centocor witness so far, just so the jury understands exactly what you've done and what you haven't done.

You said you're a patent lawyer, correct?

A. Correct.

Q. Not a scientist, correct?

A. I have a scientific background, but I am not a scientist.

Q. Right. So you have not yourself done any work to isolate an anti-TNF-alpha antibody, correct?

A. No.

Q. Never isolated a mouse antibody, correct?

A. Correct.

Q. Never isolated a chimeric antibody, correct?

A. Correct.

Q. Never isolated a fully human antibody, correct?

A. Correct.

Q. Now, you are, as you told us, a patent lawyer, and you've been at Centocor for some time, correct?

A. Yes.

Q. Since 2001, you have been supervising patent work at Centocor, correct?

A. Correct.

Q. That includes both litigation against the parties and prosecution, correct?

A. Correct.

Q. And in 2001, you were supervising the prosecution of the patent that became the '775 patent, correct?

A. Not directly.

Q. You were supervising someone named Kevin Townsend, correct?

A. Correct.

Q. And he was the patent lawyer within Centocor who decided to file the application in 2002 that led to this patent, correct?

A. The patent application was filed by outside counsel. Kevin was working with them.

Q. So the person who was supervising Mr. Townsend at Centocor, when the decision was made to file the 2002 patent application, was you?

A. Correct.

Q. All right. Now, let's go to the conversations that you had with Abbott.

You had three conversations with Abbott before the commencement of this litigation, correct?

A. Right.

Q. And you understand that Ms. Elderkin and I are exploring this, because there's a question of whether Centocor has given notice to Abbott of its charge of infringement, correct?

A. Yes, I understand.

Q. So let's see what you said during these conversations.

All three were telephone conversations, correct?

A. Yes.

Q. Two were with a man named Mr. Conway, correct?

A. Right.

Q. And one was with a Mr. Deberadine, correct?

A. Deberadine, yes.

Q. Let's start with the conversation with Mr. Conway. Now, this occurred around December 13th, 2005, correct?

A. December 2005, correct.

Q. That was right after the claims had been allowed by the United States Patent Office, correct?

A. Right.

Q. The patent hadn't actually issued yet,

correct?

A. Correct.

Q. You didn't give Mr. Conway a copy of the patent, did you?

A. No. I referred him to -- I gave him the patent application number, and I referred him to the Patent Office website where he could pull up the entire file.

Q. Do you know whether the entire file was available on December 13th of 2005?

A. I believe it was.

Q. And other than telling Mr. Conway you can go to the website and get the patent for yourself, you had no discussion with him on the substance of the '775 patent in that first conversation, correct?

A. That's right.

Q. And you didn't tell him that Humira infringes, correct?

A. Not in that conversation.

Q. Now, let's go to the second conversation. That occurred on January 6th, 2006, correct?

A. Correct.

Q. This is a telephone conversation again, correct?

A. Yes.

Q. Mr. Conway said to you: Do you have any testing that shows competitive analysis with Humira, correct?

A. Correct.

Q. Now, you told Ms. Elderkin that you had testing.

That testing was with cA2 and Humira, correct?

A. At that time, yes.

Q. It was not testing with A2, correct?

A. Correct.

Q. But you did tell him you had testing, correct?

A. Right.

Q. Mr. Conway said to you: Would you give us the testing so we can evaluate the testing, correct?

A. He asked us -- yes, he asked if we would give it to him.

Q. And you said you would take it under advisement, and you would get back to him, correct?

A. Correct.

Q. But you never got back to him, did you, sir?

A. No.

Q. So what happened was, you had a conversation with Mr. Conway; he asked you for the testing; you said you would get back to him; and then you sued, correct?

A. It was quite some time after that that the

lawsuit --

Q. So when Ms. Elderkin referred you to Abbott getting access to the tests, it was only after Abbott had been sued, correct?

A. Right.

Q. And it was only as part of the formal discovery process that's guided by His Honor's rules, correct?

A. Right.

Q. Now, let's talk about the third conversation with Mr. Deberadine; is that correct?

A. Yes.

Q. Also by telephone, correct?

A. Right.

Q. That occurred in February of 2006, correct?

A. Correct.

Q. And he told you that he had looked at the '775 patent, and he thought and Abbott thought it was not valid, because it wasn't enabled, correct?

A. He said he thought it was a weak patent and wasn't worth very much.

Q. And he said it was not enabled, correct?

A. He said it had enablement issues.

Q. Right. You disagreed with him, correct?

A. I disagreed.

Q. When he asked you why you disagreed, you never told him, did you?

A. I told him we disagreed; we thought it was enabled.

Q. Right. And beyond that, there was no substantive discussion between you and Mr. Deberadine, correct?

A. That was about the length of the conversation.

Q. All right. And I've now covered all of your conversations with anybody, other than Abbott -- at -- strike that. I'm sorry.

I've now covered your conversations with anyone at Abbott concerning the '775 patent before the lawsuit was filed.

A. Those were the only conversations I had, although there were a lot of discussions going on at another level.

Q. I understand that. But you can only tell us about what you participated in.

A. That's correct.

Q. And I have now covered what you participated in, correct?

A. Yes.

Q. Now, let's go to the licensing issue that Ms. Elderkin asked you about.

You actually supervised patent licensing on behalf of Centocor, correct?

A. Yes.

Q. You have since 2001, correct?

A. Yes.

Q. You have participated in many different licensing negotiations, correct?

A. That's correct.

Q. And as part of that, you're familiar with a concept called a royalty offset, correct?

A. Yes.

Q. Royalty offset means that if I take a license from Ms. Elderkin, but I happen to be paying Mr. Sayles and Mr. Beck royalties, I can offset those against what I owe Ms. Elderkin, right?

A. Can I have that question back again?

Q. Sure.

A. I lost my train.

Q. Fair enough. Let me start over, and I'll break it down. It may have been too complicated. Let me ask you to assume that I have a license to Ms. Elderkin and I owe her 2 percent.

Do you have that in mind?

A. Yes.

Q. But there's a royalty offset provision.

You know what that is, correct?

A. Yes.

Q. And it says that I can offset royalties that I'm paying others.

A. Right.

Q. Do you have that in mined?

A. Right.

Q. So I'm paying Mr. Sayles 1/2 percent. Do you have that in mind?

A. Right.

Q. I'm paying Mr. Beck 1/2 percent, correct?

A. Yes.

Q. A royalty offset means that I can take those two, which equal 1 percent, and reduce what I owe Ms. Elderkin into 1 percent, correct?

A. That's generally the concept.

Q. Now, you talked about a negotiation you had with Abbott in which Abbott agreed to take a license to you, to an NYU patent, correct?

A. To a Kennedy patent.

Q. I'm sorry. To a Kennedy patent, correct? And that patent is not involved in this case, correct?

A. Correct.

Q. But it's another patent that concerns TNF antibodies, correct?

A. Right. It concerns these -- of them with Methotrexate.

Q. And when identified this patent owned by Kennedy, licensed to you, it went and sought a license, didn't it?

A. That's right.

Q. Right. So when Abbott thinks there's someone's patent out there and that they need to use that patent, based upon your experience, they come and say we'd like to negotiate a license, and that's what they did with Kennedy, correct?

A. They did that with the Kennedy patent.

MR. LEE: Nothing further, Your Honor.

MS. ELDERKIN: A few more, Your Honor?

THE COURT: Yes, ma'am.

REDIRECT EXAMINATION

BY MS. ELDERKIN:

Q. Mr. Dow, I want to make sure the jury understands the concept of the claims being allowed. When the claims of the '775 patent, when you received notification that they were allowed in December of 2005, was that some kind of official notification from the Patent Office?

A. Yes. The Patent Office issues what they call a notice of allowance, and that is a paper from the

Patent Office that tells you that your patent is basically going to issue.

Q. And why did it take six months for it to issue then?

A. Well, after that, you have to pay an issue fee to the Patent Office, and then they have to issue the patent. It takes some time for them to print it and format it.

Q. And did -- the claims issued in the patent, were they identical to the ones that were allowed in December of 2005?

A. Yes.

Q. Okay.

MS. ELDERKIN: Thank you very much, Your Honor.

MR. LEE: Nothing further, Your Honor.

THE COURT: You may step down, Mr. Dow.

MS. ELDERKIN: May the witness be excused, Your Honor?

THE COURT: Any objection?

MR. LEE: None, Your Honor.

THE COURT: All right. You're excused.

Who will be your next witness, Mr. Sayles?

MR. SAYLES: May it please the Court.

At this time, we would read into the record and for the jury the Stipulated Fact No. 18.

THE COURT: Okay.

MR. SAYLES: This is stipulation between the parties.

On March 5th, 2008, an arbitrator ruled that Abbott does not have a license to take any action with respect to Humira that would constitute an infringement of the '775 patent. Except that with respect to Humira that qualifies as co-administration product under the license agreement, Abbott has a license to take any action that would constitute infringement of the '775 patent.

That concludes Stipulation 18.

Our next witness is John Conway by deposition, and I will read the agreed-upon introduction of Mr. Conway.

John Conway. Mr. Conway is a former in-house patent attorney for Abbott. Mr. Conway worked first for BASF, starting in 1999, as an in-house patent counsel. Abbott eventually purchased BASF, and Mr. Conway continued to work for the company through July of 2008.

During his tenure with BASF and Abbott, Mr. Conway had some responsibility for Abbott's Humira

product. Mr. Conway now works for another pharmaceutical company.

(Video playing.)

QUESTION: As part of your responsibilities at Abbott, were you part of a team, or did you give input to a team that came up with a strategy for dealing with IP issues in connection with biologics?

ANSWER: Yes.

QUESTION: Plaintiffs' Exhibit 391 is a copy of a document bearing production numbers ABT00332668 through 332792.

If you can turn, then, to Page 41, which is ABT00332708. Tell me when you're ready for a question.

ANSWER: Uh-huh. Okay.

QUESTION: So the conclusion refers to a number of biologics projects that Abbott has at different stages of research and development, right?

ANSWER: Right.

QUESTION: And if we look at the next page, one of those is Humira, right?

ANSWER: Right.

QUESTION: And one of the conclusions with respect to -- or one of the conclusions that's set

forth in this document is that Abbott can make the best use of this resource by identifying the most attractive targets from a commercial, clinical, and scientific perspective and using an aggressive risk management strategy to obtain freedom to operate, right?

ANSWER: Right.

QUESTION: And that conclusion applies to the biologics projects at different stages of research and development that are identified on the next page, right?

MR. MCELWAIN: Objection.

ANSWER: Generally -- in general, you would read that as applying to all of these.

QUESTION: So it would apply to Humira, right?

MR. McELWAIN: Objection.

ANSWER: It could.

QUESTION: So on December 15th, 2005, you asked Zehra Kaymakcalan for data for the purpose of rendering legal advice about the Centocor patent, right?

ANSWER: Right.

QUESTION: And you gave her the patent claims that were going to issue as the '775 patent, right?

ANSWER: Right.

QUESTION: And on the 16th of December of 2005, Zehra Kaymakcalan provided you with the technical information that you wanted so that you could provide legal advice regarding the Centocor patents, right?

ANSWER: Right.

QUESTION: Within a week or two after you were notified by Ken Dow that the '775 patent was going to issue, you started getting legal advice from Larry Pope about that application, right?

ANSWER: Okay. Yes.

QUESTION: At least by February 13th of 2006, you realized that it was possible that Centocor was going to sue you for infringement of the '775 patent when it issued, right?

ANSWER: Yes.

QUESTION: And within two days after that, meaning after February 13th, 2006, you started also receiving advice from Winston & Strawn, outside counsel, concerning the Centocor patent, right?

ANSWER: Right.

QUESTION: And by October of 2006, you sought advice from yet another outside counsel, right?

ANSWER: Are you referring to Edwards Angell?

QUESTION: Correct.

ANSWER: That's correct.

QUESTION: So in October of 2006, you went to at least a third outside counsel to ask for advice concerning the Centocor patents and Humira, correct?

ANSWER: Correct.

(End of video clip.)

THE COURT: Does that end the offer on this?

MR. SAYLES: It does, Your Honor.

And may it please the Court.

Mr. Conway's deposition played 4 minutes and 53 seconds, and it all goes to our side of the ledger.

THE COURT: Okay. I got it.

MR. BECK: We have no objection to that, Your Honor.

MR. SAYLES: Your Honor, at this time, we would call, as our next witness, Cheryl Lubbert. And I will read the agreed-upon introduction of Ms. Lubbert.

Cheryl Lubbert is currently the Divisional Vice President of Abbott's immunology franchise. Ms. Lubbert is responsible for making all marketing decisions for Humira in the U.S.

Ms. Lubbert testified at her deposition

as a corporate representative on behalf of Abbott regarding the date on which Abbott became aware of the Centocor patent and the facts and circumstances surrounding such awareness.

(Video playing).

QUESTION: Focusing strictly on the manufacture of the bulk drug substance, also known as D2E7, can you identify all entities that are involved in the manufacture of the bulk drug substance at Abbott?

ANSWER: All entities that are involved in bulk drug substance include ABL Puerto Rico branch and also ABC. They're not on the list.

Oh, yes, they are; ABC.

QUESTION: So for any Humira that's sold anywhere in the world, the bulk drug substance is either produced at Abbott Bioresearch Center in Massachusetts, or Abbott Biotechnology Limited in Puerto Rico, correct?

ANSWER: Yes.

QUESTION: What is -- what is your current title?

ANSWER: Divisional Vice President, Immunology.

QUESTION: Who at Abbott is ultimately responsible for all marketing matters related to Humira?

ANSWER: Could you clarify your question?

Are you talking about international, or are you talking about the U.S.?

QUESTION: Let's focus on the U.S.

ANSWER: In the U.S., ultimately for Humira, I would be.

QUESTION: When did Abbott first become aware of the Exhibit 1 patent, which is United States Patent 7,070,775?

ANSWER: My understanding is that we became aware when it was issued.

QUESTION: On the day it was issued?

ANSWER: I don't know if it was the exact day, but I believe it was in the time period of when it was issued, around July of 2006.

QUESTION: Was it the day after it issued?

ANSWER: I don't know.

QUESTION: Do you know who at Abbott was the first person to become aware?

ANSWER: I believe that it was Paul Yasger.

QUESTION: Is Mr. Yasger an attorney at Abbott?

ANSWER: Yes, he is.

QUESTION: Did you speak to Mr. Yasger in

preparation for today's deposition?

ANSWER: Yes, I did.

QUESTION: Did you ask him how he became aware of the '775 patent?

ANSWER: Yes, I did.

QUESTION: What did he tell you?

ANSWER: He told me that he became aware when it was issued and that was really the extent. He didn't say how he became aware.

QUESTION: Sure.

Was Abbott aware of the '775 patent application when it was pending in the Patent Office prior to its issuance?

ANSWER: My understanding is that Abbott personnel became aware during a meeting at J&J in December of 2005, where J&J told Abbott personnel that they had obtained an allowed application that could affect Humira.

QUESTION: Did Abbott obtain the allowed application prior to its issuance in July of 2006?

ANSWER: My understanding is that the application was given at the time that that discussion occurred. I'm not sure what patent it was for, though. I can't -- they didn't say, because at the time, there was obviously no number.

QUESTION: But it's your understanding that at a meeting between Johnson & Johnson and Abbott, Johnson & Johnson provided Abbott with a copy of the application that became the '775 patent?

ANSWER: My understanding is that J&J told Abbott that they had obtained an allowed application that could affect Humira.

QUESTION: And they also provided a copy; is that right?

ANSWER: That's -- that's the best of my knowledge. I think they did.

(End of video clip.)

MR. SAYLES: That concludes the Cheryl Lubbert deposition. It was 4 minutes and 5 seconds, and that will go to our ledger as well.

THE COURT: Thank you.

Still no objection to that, Mr. Beck?

MR. BECK: Still no objection.

MR. MASLOWSKI: May it please the Court, Your Honor. Plaintiffs call Rob Bazemore.

THE COURT: Okay.

COURTROOM DEPUTY: Would you raise your right hand, please.

(Witness sworn.)

MR. MASLOWSKI: Your Honor, before we get

started, Plaintiffs would like to offer into evidence PX251, 261, and 704. They are not on the preadmitted list.

We understand that Abbott has withdrawn their objections to those exhibits.

THE COURT: Is that correct?

MR. LEE: That's correct.

THE COURT: All right. Those three exhibits are now received into evidence.

Did you get those numbers, Ms. Dupree?

Okay.

ROBERT BAZEMORE, PLAINTIFFS' WITNESS, SWORN

DIRECT EXAMINATION

BY MR. MASLOWSKI:

Q. Good morning, Mr. Bazemore.

A. Good morning.

Q. Can you please tell the jury a little bit about yourself.

A. I can. My name is Rob Bazemore. I grew up in a little town outside of Savannah, Georgia. Ultimately went to the school at the University of Georgia where I received a degree in biochemistry, a bachelor's degree in biochemistry.

I went from there to work with Merck & Company, where I worked for about 11 years. During that

time, I lived in New Orleans and worked on my MBA degree, a master's in business, at Tulane University. I now live just outside Valley Forge with my wife and two kids, and work for Centocor Ortho Biotech.

Q. Mr. Bazemore, are you currently employed?

A. I am, yes.

Q. You just said you worked for Centocor Ortho Biotech; that's right?

A. That's correct.

Q. And we'll call it Centocor today?

A. That's fine.

Q. And what is your current title at Centocor?

A. I am the Vice President of Marketing for the immunology franchise.

Q. And can you please tell us what is the immunology franchise?

A. Immunology is a therapeutic area, and it means that I have responsibility for the two products, Remicade and Simponi.

Q. And in your work in that respect, what exactly do you do?

A. Well, I have overall promotional responsibility for those two products, which means that I have responsibility for all the promotional efforts, the educational efforts, how we educate physicians about

the compounds.

In order to do that, we develop marketing strategies that's based on lots and lots of market research. We spend millions of dollars a year understanding our customers, understanding how these products are used, understanding the disease states, and how the product can best be used to treat those disease states.

So we really spend a lot of our time doing analytics in best understanding how to address the needs of our customers.

Q. Now, how long have you had responsibilities related to the marketing of Remicade?

A. Since I joined Centocor in January of 2002.

Q. And Centocor is the entity that sells Remicade in the United States, correct?

A. That's correct.

Q. How does Centocor market and sell Remicade in the U.S.?

A. Well, our primary audience is the physicians, because these are drugs that treat very serious diseases. So we primarily target the physicians. We use professional representatives as well as medical affairs, people that work in the field. We also use other media, like journal advertising, the internet, et

cetera.

To a lesser degree, we sell Remicade directly to patients through TV advertising, print advertising, and that kind of thing.

Q. So you indicated that your primary audience is physicians. Are there particular types of physicians that you market and sell Remicade to?

A. Most of our efforts are directed at the rheumatologists, the gastroenterologists, and the dermatologists.

Q. And why is that?

A. Because those are the physicians' specialties that treat the diseases that Remicade is approved by the FDA to treat.

Q. And can you please explain what you mean a little bit further, please?

A. I can. In fact, I prepared a slide. I'm not sure -- here we go.

Q. You should have the ability to click through right there.

A. Okay. So I prepared this just to explain the three disease areas that we cover and the specialists that we currently sell Remicade to.

The first on the chart is the gastroenterologists. They, of course, do a lot of

things, but one is that they treat a group of diseases called inflammatory bowel diseases. Two of those are Crohn's disease, or CD, and ulcerative colitis, or UC. Remicade is approved to treat both of these indications.

The second specialty that I mentioned that we call on is the rheumatologists, who, again, they do a lot of things, but one is that they treat rheumatic conditions, namely rheumatoid arthritis, or RA, ankylosing spondylitis, or AS, and psoriatic arthritis, or PsA.

Again, these are all three diseases that Remicade is indicated by the FDA and approved to treat.

And then the final specialty is the dermatologist, who treats a number of cosmetic conditions, but also medical conditions like psoriasis, or PsO.

Q. Are you familiar with Humira, the product accused of infringing Centocor's patent in this case?

A. I am, yes.

Q. Just in general, how do you understand that Humira works?

A. Humira works essentially the same way as Remicade. It targets TNF; it targets tumor necrosis factor. It's a monoclonal antibody much like Remicade.

Q. Now, looking at your chart, do you know which

of the diseases identified in your chart that Humira is approved to treat?

A. Yes. Abbott, more or less, followed the same kind of development path that Amgen followed for Enbrel and we followed for Remicade.

Humira is approved to treat all the same diseases that are on this chart, with the exception of ulcerative colitis. Humira is not approved to treat UC.

Q. So if we remove ulcerative colitis from your list, this shows all the diseases where Remicade and Humira have overlapping approvals; is that right?

A. That's right.

Q. Now, let's focus on the five diseases that are identified in your chart.

A. Okay.

Q. And let's start with the approval dates for each product.

A. Okay.

Q. Each of the products.

Do you have a slide that summarizes that?

A. I do. And this may be one that's been used already, but this essentially shows the five disease states that both products are indicated and are approved by the FDA to treat.

There are two things that it shows. The

approval dates for both products. Remicade was first approved in August of 1998, followed by Humira about four and a half years later, on December 2002.

The other thing it shows is the approval dates and the indications that Humira has for all the same indications; essentially came after Remicade had been approved and the same indications.

Q. Are you generally aware of the manner in which Abbott sought approval for indications?

A. I am, yes.

Q. And have you followed Humira's approvals for these indications?

A. Very closely.

Q. How, if at all, were Abbott's attempts different from Remicade's attempts to seek approval for these diseases?

A. Well, I think if you look at the clinical trials that Abbott did with Humira, they more or less were the same types of trials that Enbrel did and Remicade did for the same approvals.

And so the claims that they have in these specific indications are very similar to the claims that Remicade and Enbrel have.

To my knowledge, there weren't any different types of studies that they did that would give them

access to different types of patients than those that had already been labeled for Remicade and/or Enbrel.

Q. If we can, let's go back to your first slide.

A. Okay.

Q. And I'd like to take a closer look at each of the diseases identified for which Humira and Remicade have both been approved.

Let's start with the first one, Crohn's disease, identified in the blue box there.

A. Okay.

Q. Yesterday we heard some testimony about what Crohn's disease is all about, but can you briefly remind us, please?

A. Crohn's disease is a disease that's characterized by inflammation of the colon, of the bowel. These are patients -- I don't know if you know anyone with Crohn's disease, but it is characterized by nausea, vomiting, intense pain. Patients have flares and have intense pain.

These are patients who are frequently up and going to the bathroom. In fact, many of these patients have to map out routes to go to work in the morning, or if they're leaving their home, where they can find bathrooms in case they have an urgent attack and have to find a way to go to the bathroom. So it really is a

disabling disease in terms of patients' quality of life.

Q. And there are different types or versions of Crohn's disease, correct?

A. There are. There is the chronic Crohn's disease of which physicians may characterize that as mild, moderate, or severe in severity.

And then there's a particular type of Crohn's disease known as fistulizing Crohn's, which is a very severe form of the disease.

Q. Can you please explain just a little bit further what fistulizing Crohn's is?

A. Fistulizing Crohn's is a special -- like I said, a severe version of the disease where the patients not only have inflammation of the bowel, but it actually forms tunnels or fistulas -- that's the name -- from the bowel out to the outside of the body.

And so you actually -- these tunnels can actually emerge in the abdomen, in the groin, in the thigh. And it basically causes the contents of the bowel to spill outside the patient's body. So as you can imagine, it's a very serious disease in terms of quality of life.

Q. Are Remicade and Humira both approved to treat both types of Crohn's disease?

A. Remicade is approved to treat both types of

Crohn's, both chronic Crohn's as well as fistulizing Crohn's.

Humira is approved to treat chronic Crohn's disease but not fistulizing Crohn's.

Q. Now, let's take a step back for a moment.

Do you have an understanding based on your work at Centocor how a patient comes to end up having to take biologics, such as Remicade and Humira, for the treatment of Crohn's?

A. Yes, I do.

Q. Can you please explain that to the jury?

A. Okay. I'll put a schematic up that may help explain this as well. The slide will advance one.

Okay. So a patient may be diagnosed as having Crohn's disease either by their primary care physician or they may be diagnosed by a gastroenterologist, if they get referred.

What typically happens is these patients have flares of the disease, and the physician may attempt to manage it with bursts of steroids, especially if they have an acute bout of the disease.

For many patients, that will be enough and the disease kind of goes away. But for many patients, it's not. And so the physician will move on to chronic therapy with a group of drugs known as immunomodulators.

There are several examples of immunomodulators, and I have listed two of them here. 5-ASA, and azathioprine. These are both drugs that have been around for a long time. They're typically cheap, and so insurance companies usually require that those be used first to see if they will manage the patient.

If a patient doesn't respond to these drugs or if they respond and lose response over time, the next class that would be used would be the biologics, like Remicade and Humira.

Q. Now, have your responsibilities in marketing -- let me get my note.

Have your responsibilities in marketing at Centocor involved assessing competition?

A. That's a primary part of my responsibility in marketing.

Q. And prior to the approval of Humira in February of 2007 for Crohn's disease, what products did Remicade compete with for the treatment of Crohn's?

A. In Crohn's disease prior to the approval of Humira, there were no other biologic products approved for Crohn's disease. So there were no other products that Remicade competed with.

Remicade had -- I would say, 95 percent of the patients were treated with Remicade. There were some

patients that were being treated with Humira. Humira had already been approved in rheumatoid arthritis, and so there was some off-label use of Humira. But for the most part, almost all patients were treated with Remicade.

Q. Did Remicade compete with the compounds identified near the top of your chart, like steroids and immunomodulators?

A. Remicade doesn't really compete with those products. As I indicated before, insurance companies many times will require those products to be used before Remicade because they're inexpensive.

And, in fact, when a biologic is given, Remicade or Humira, oftentimes those products are not discontinued. They continue to be used. So they're precursors to biologics. They're not necessarily competitors.

Q. Now, once Humira was approved for treating Crohn's in February of 2007, did Remicade and Humira begin to compete?

A. Very much so. I would say Humira is Remicade's only competitor in Crohn's disease.

Q. Now, you indicated that the two products compete in Crohn's disease.

What gives you that understanding?

A. Well, as I said, when you asked me about my marketing responsibilities and what I do as a Vice President of Marketing, a big part of what we do is gather competitive intelligence. We do lots of market research with our physicians and patients to understand how these products are being used and why, why they're making the decisions that they are.

So that kind of data tells us how Humira is being used, how Remicade is being used, and how they compete with each other.

Q. Now, based on that data, are there particular product features or attributes that patients and doctors look at when deciding which of these products to use?

A. I think there are probably a number of factors that come into play when a physician and patient are deciding what's right.

The first is, of course, the drug has to be effective. They have to think that the drug is going to work in that particular patient and is safe for use in that patient.

The second oftentimes is affordability, whether the product is affordable to the patient that he's seeing.

The third may be the route of administration. If it's an IV or a subcu and if the patient has a

preference for one versus the other. Frequency of administration oftentimes comes into play. Would the patient rather give a drug to themselves more frequently or come into the office and get it less frequently. These are factors that all play into -- I think probably play more strongly if it's the first biologic the patient has ever been given.

There's another group of patients, though, who's already been on one of these drugs and is switching for some reason. Maybe it didn't work, or they had a safety issue around it. And I would say in that case, the main issue was whether or not the drug works.

And so those factors probably play more on a first-line patient, a patient who's never been on a biologic than in a patient who's switching and really is just trying to find a drug that works well for them.

Q. Let's look at each of those features a little bit more closely.

First, with respect to efficacy, what, if any differences, are there in terms of perceived efficacy between Remicade and Humira for treating Crohn's disease?

A. Specifically for Crohn's?

Q. Yes.

A. In Crohn's disease, so we gather a lot of research, as I said, that looks at perceptions. I think that there are two things that make Remicade perceived by gastroenterologists as being a more effective drug in Crohn's disease.

One of those is the fact that it's approved to treat both Crohn's and ulcerative colitis, both of which are inflammatory bowel diseases, as I showed at the beginning.

Humira is only approved to treat Crohn's disease.

I think the second is that, because Remicade is approved and has shown effectiveness in treating fistulizing Crohn's, which is that very severe form of Crohn's, and Humira is not. I think that there is a perception amongst physicians that Remicade is a more potent drug, a more effective drug in treating Crohn's.

Q. Can you please take a look at PX261, which I believe is in the book there?

A. Okay.

MR. MASLOWSKI: Joe, if you can put it on the screen, please.

Q. (By Mr. Maslowski) What is Exhibit 261?

A. Exhibit 261 is an example of a market research study that we do on an ongoing basis called PhysPulse.

This is done amongst physicians, and we basically ask them questions about their perceptions of different drugs.

We try to understand how they're using them, why they're using them, why they make the decisions that they are, and how they perceive the different products.

THE COURT: We have to slow down. Let me call you back to your days of your youth when you were raised in Georgia. She just cannot stay up with you.

THE WITNESS: I have to say this is the first time I've been asked to slow down.

THE COURT: Please do. Thank you.

A. One other thing I'll point out on this chart is that you see that in the subtitle it says W32. That means Wave 32. We do these studies between one and three times per year, depending on how quickly the market is evolving so that we can see how things change over time.

So that means that this is the 32nd consecutive wave of this study that we've done in gastroenterology.

Q. (By Mr. Maslowski) And is this the type of data you mentioned before that indicates to you that Remicade and Humira are competing in Crohn's disease?

A. It is.

Q. Can you please turn to Page 9?

Is there anything on this page which will help you explain to the jury the differences in perceived efficacy?

A. Yes. So if we're talking about efficacy, if you go to the right-hand side where it says product performance, there are two charts that are featured there.

And there we're looking at two separate things: Efficacy, that is, the effectiveness of the drug, how it works, and safety.

The way the study works is that we essentially ask physicians to rate compounds on a scale of 1 to 10, where 1 means poorly satisfied with that particular attribute; 10 means it's very effective in satisfying that attribute.

Then what we do is we score the number of physicians who rate it an 8, 9, or 10. And that's what's written on the left-hand side, percent of physicians rating it 8, 9, or 10. So these are the ones who say that product does a very good job on that attribute.

And it's hard to see the line, the light blue line at the top, but it's the one where you see the numbers that say 53, 63, 56. The line is very faint,

but that's essentially Remicade.

And you can see that they rate Remicade higher than Humira or the other products that are clustered down lower in terms of perception of efficacy.

The other thing I will note about that is you see the starburst out beside the numbers 41 and 37. Those are the other compounds: Humira, immunomodulators, et cetera.

What that means is that that number is statistically significantly different, and so physicians significantly ranked Remicade higher on efficacy than Humira or immunomodulators or steroids or the other products in the class.

MR. MASLOWSKI: Joe, maybe you could trace the top line. It's kind of hard to see on the exhibit. Just to help the jury.

Q. (By Mr. Maslowski) You also mentioned this exhibit shows safety data as well.

What, if any, differences in perceived safety are there between Remicade and Humira for treating Crohn's disease?

A. Well, I think that physicians regard all of these products as being safe amongst the patients that they treat or they wouldn't choose that drug for that patient.

If you look at the labels between Humira and Enbrel in terms of the label is what the FDA will allow us to actually say or promote in terms of safety, the labels between Humira and Remicade are actually very similar. And the language in the kinds of adverse events that are included in them are almost the same.

And so I think amongst gastroenterologists, the perception is that there aren't any differences between them in terms of safety. So I can go to this chart, and this kind of illustrates my point, if I go to the bottom of the chart instead of the top.

Now we're looking at overall safety. Same thing; this is a 1-to-10-point scale, and we pull those physicians out who say the product is an 8, 9, or 10.

So it's very satisfactory on that parameter. Now all the products -- and it's, again, hard to see with the colors of the lines -- but you see the numbers to the right: 29, 29, 28. That's where Remicade and Enbrel and Humira, they're all there together. And there's no starburst amongst them.

So it basically says there's no significant differences perceived by physicians on the parameter of safety.

The only one that's significantly worse is the red line on the bottom, which is steroids, and you see

the starburst by the steroids.

Q. Another feature that you mention that doctors look at when prescribing these products is the route of administration, correct?

A. That's correct.

Q. Do Remicade and Humira have different routes or modes of administration?

A. They do. Remicade is given by an intravenous infusion, and Humira is given by subcutaneous injection to the patient.

Q. Let's focus on Remicade's route of administration for a moment.

A. Okay.

Q. Can you please explain a little bit further what you mean by IV infusion?

A. Sure. So to get a dose of Remicade, the patient would go to a physician's office or to some other kind of infusion center. Remicade is mixed in a bag and the needle is put in their arm. And they essentially sit while the drug is administered over a period of about two hours.

Q. You mentioned infusion centers. What's an infusion center?

A. Well, an infusion center can take a number of forms. Many physicians set these up in their offices so

the patient just goes directly to the physician's office.

It could also be an infusion center that's set up specifically for doing that, or there are some infusion centers that are set up in hospitals.

Essentially, what they're like, when the patient goes there, is there will be -- in most cases, there will be a comfortable chair for the patient to sit. It may be a reclining-type chair. They usually have televisions available so that they can watch television or read magazines.

Many patients like to talk with each other while they're getting the infusion. But the whole process is overseen by a nurse. So there is, you know, care given to the administration of the drug.

Oftentimes, as I said, the infusion center is actually in a physician's office, and so they'll schedule the infusion around their regular physician follow-up. So they'll get to see their physician, assess how well the disease is doing and how well the drug is doing in terms of treating their disease.

Q. Now, what is the mode of administration for Humira again?

A. Humira is a subcutaneous injection that the patient gives to themselves.

Q. Can you explain that a little further, please?

A. I can. So, basically, the way a patient would go about doing that is instead of coming to see the physician in their office, the physician writes a prescription for Humira, and the patient takes that with them.

The drug is either shipped to them from a specialty pharmacy, or they can actually take it to a retail pharmacy that they use, and they will get the product filled.

Usually, what they do is they'll give them several doses at once, meaning several months' worth of the supply. So they'll take those home and they'll put them in the refrigerator, because the products -- both products have to be kept cold.

When it's time to administer it, they will oftentimes take the Humira out of the refrigerator and let it warm up a bit. It hurts a little if it goes in too cold. And they essentially just inject themselves. And once they're done, the needle is essentially a sharps at that point, so they have to dispose of them appropriately. So patients will have some sort of a sharps disposal container. You've probably seen these red plastic boxes in a hospital.

They put them in there so that children or

pets or whatever can't get into them. And then when the box is full, they find some compliant way to dispose of the syringes.

Q. Can you just throw them in the garbage?

A. No, you can't. It's illegal.

Q. Let's compare the two modes of administration. Are there benefits associated with the IV infusion route versus the subcutaneous administration?

A. I would say there are a number of advantages to IV.

The first is that the procedure is done and overseen by a nurse or other healthcare practitioner, so there's very few chances of messing it up in any way or the patient not getting the appropriate dose.

Also, because they're in a physician's office, they have an opportunity to interact with their physician. The physician can check their disease state. They can also oversee the procedure and make sure that there's no adverse events that occur when they're getting the drug.

Q. Are there benefits associated with subcutaneous administration versus IV infusion?

A. Yes, there are.

For patients who choose to self-administer, the advantage is that they have the drug at home; they

don't have to schedule a follow-up visit with the physician; and they can choose just to inject the drug to themselves whenever they want to at home at their own leisure.

Q. So there seem to be benefits to both. What do patients and doctors prefer, which one?

A. Well, I think what we find in all of our market research is that that's an individual preference. What works best for me may not work best for you. Some patients would prefer to go to their physician's office and have the entire thing done by a nurse. Some patients would prefer to inject the drug themselves. We follow this very closely, of course, because it's one of the ways that we analyze the marketplace. And what we see is that about 15 to 25 -- 15 to 20 percent of patients have a strong preference for the infusion. They would rather go and have the physician give the drug to them.

If you look at this as kind of a sliding scale or a spectrum, it's about 15 to 20 percent on one side. There's about another 40 percent on the other side, who actually prefer the subcutaneous, and they would much rather have the convenience of giving the product to themselves at home.

But then there's a group in the middle of

about 40 percent that don't have a strong bias one way or the other, and there are usually other factors that will come into play in terms of deciding which drug they get.

Subcutaneous or IV is one, but it's probably not the most important factor.

Q. So in terms of the way that Centocor actually sells Remicade, does Centocor segment the market and only target the people that like IV infusion as compared to the people that like subcutaneous?

A. No. I think we think of the market as there's two types of patients that we sell Remicade to.

There are patients who have never been on a biologic before, and they're making their decision for the first time to go a biologic, and then there are patients who have been on a biologic, and maybe they failed or they didn't respond as well.

We sell Remicade to both types of patients. The reason each of those would choose a drug, of course, are a little bit different, but the fact that it's IV or subcu doesn't mean that we only sell to a group of patients that prefer subcu, because as I said before, not all patients have a really strong bias one way or the other.

Q. Have you heard the term compliance used with

respect to these biologic products?

A. I have, yes.

Q. And what does compliance mean?

A. Compliance just means whether or not a patient takes the drug as it was prescribed by the physician or as the label indicates that it should be taken.

Q. Are there any compliance issues with respect to the different modes of administration?

A. There could be. I mean, for a patient who's getting an infusion in the physician's office, there's a higher chance they're going to be compliant because the drug is actually being given by a nurse. So there's a higher likelihood that it will be given as instructed. Oftentimes, if a patient misses an appointment or they miss their infusion, the office staff will call them, they'll follow up, remind them, and get them back in, if something happened or they just missed their appointment.

With a subcutaneous product, you all know that when you have a drug at home, sometimes you can forget a dose. You take it a day after you should have, or, you know, there's sometimes that you just forget to do it exactly the way that the label had indicated.

So there can be differences between the products on compliance.

Q. And you also mentioned frequency of administration as another fact that goes into the prescribing decision.

What did you mean by that?

A. The frequency of administration just has to do with how often the patient has to take a given drug in a month.

Q. And can you explain the dosing frequencies of Remicade versus Humira for treating Crohn's disease?

A. So for Crohn's disease, after getting through the initial set of doses, Humira's given every two weeks. The patient injects themselves at home every two weeks.

Remicade is given every eight weeks. So they would essentially go to the doctor's office once every two months, and there's no other drug administration of Remicade in between the two doses -- in between those doses.

Q. So what does that mean over the course of a year?

A. Well, if you averaged that out over the course of a year, it means that a patient will essentially get between 6 and 7 doses of Remicade over a year compared to 26 doses that they inject themselves with Humira over a given year.

Q. Is the cost to the patient a factor that goes into the prescribing decision?

A. It's a very important factor.

Q. And can you please explain that a little bit further.

A. Well, there are -- I guess there are two components of cost.

The very first one is whether or not a patient's insurance company will even cover the drug. If you are a patient and your insurance company didn't cover Remicade, you would be not likely to take that drug because it would be very expensive if you had to pay 100 percent of the cost. And so that can drive you to one or the other.

If your insurance company covers both, sometimes the insurance companies will actually prefer one drug over the other, and they'll assign an out-of-pocket co-payment.

You all know, if you've gone to pick up a prescription at the pharmacy, usually, you have to write a check for 15 or 25, $30, some amount as a co-payment. That amount is set by the insurance company, and it usually is based on which drugs they prefer.

And so one drug can be more expensive from a co-payment standpoint than the other.

Q. Let's look specifically at Remicade versus Humira. Which costs more to the patient?

A. Well, I think to answer that, it's important to separate out Medicare patients versus patients who are on a commercial insurer.

For Medicare, Medicare used to not cover prescription drug benefits up until about the mid-2000s. There was a law passed then, and now all prescription drugs are covered by Medicare.

There are differences in the amount of out-of-pocket that a patient has to pay for a prescription drug versus an infused drug. And on an annual basis, Remicade tends to be cheaper for Medicare patients, which is sometimes important for patients who are on a fixed income.

On the commercial side, again, as I said, insurers may favor one drug or another based on which ones they have a preference that the patients use. And some plans, Humira's more expensive to the patient; in some plans, Remicade is more expensive to the patient. So overall, I would say, from a commercial insurer standpoint, it's roughly equal.

Q. Now, let's take a step back. We've looked at a lot of factors here that go into the prescribing decision.

Which of those factors is the most important factor when deciding between Remicade versus Humira?

A. Well, as I said before, I don't think that any one of those is the most important factor. It depends on the particular patient.

If -- you know, if I'm a patient and my plan, my insurance company, doesn't cover Humira, and I want Humira, it would be irrelevant that I prefer subcu, because I'm not going to pay the full cost of the drug out-of-pocket. And so in that case, cost would be the major factor.

And if I'm a patient who's already failed on a particular drug, my most important concern is that the next drug work, particularly given the severity of these diseases.

And so, again, depending on the patient, each of these factors can play more or less a different level of importance.

Q. Is the same true for doctors; some doctors look at certain features as more important as compared to others?

A. I think that's generally true, but if you look at the prescribing, most physicians write both products. Most physicians, regardless of the specialty, write both Remicade and Humira in their practices.

Q. Now, we've been talking about how Humira competes with Remicade in Crohn's disease. Are there other biologic products in Crohn's disease?

A. There are two other products that currently compete in Crohn's disease. The names of those are Tysabri and Cimzia.

Q. Can you briefly tell us what Cimzia is, please?

A. Again, Cimzia is always an anti-TNF product. It is not a monoclonal antibody. It's actually built a little bit differently. It's a molecule. But it does target the same tumor necrosis factor.

Q. And how is it administered?

A. In Crohn's disease, the indication that was approved by the FDA was -- it was in a syringe, much like Humira, but the patient had to go into the physician's office and have the physician give it to them. They couldn't self-administer.

Q. So a patient can't self-administer Cimzia at home like he or she could with Humira, correct?

A. They could not.

Now, Cimzia was just approved in rheumatoid arthritis, which we'll talk about later. When they got that indication, they got the ability to be self-administered by the patient.

But everything up until about a month ago, the patient had to go into the gastroenterologist and have them give the drug.

Q. And when was Cimzia launched?

A. Cimzia was launched in April of 2008.

Q. And that was for Crohn's disease?

A. For Crohn's.

Q. Based on your experience, can you describe the impact that Cimzia had when it was launched in Crohn's disease?

A. Again, I said -- as I said earlier, I think Remicade and Humira really are the primary competitors in Crohn's. Cimzia has had a very minor impact on the market overall, and their market share is a relatively modest one.

Q. And you mentioned a product called Tysabri.

A. Yes.

Q. What is Tysabri?

A. Tysabri is also -- it's a different mechanism entirely. It does not target tumor necrosis factor. It's a product that was launched, and it was actually pulled off the market because of a safety concern and then relaunched back in Crohn's disease but with a lot of restrictions.

And so it's a product that's not really been

used that much in Crohn's disease.

Q. Now, have you prepared a slide to show the market shares of these various products in Crohn's disease?

A. I have. Okay.

Q. Can you please explain what is shown here?

A. So this is showing -- and as I said before, there are two types of market research that we do. One is we track physicians' perceptions, and I explained some of that data. We also track the actual prescriptions, though, so that we can understand how products are being used.

This shows the actual shares or how often our product's being used. Looking at the end of 2005, which was before Humira was approved, compared to the end of 2008, which is just the end of last year, in 2005, as I said, even though Humira was not approved for the treatment of Crohn's disease, it was approved in the market for RA, and so there was some off-label use, about 3-1/2 percent of patients.

By the end of 2008, you can see that Humira now is used to treat about a fourth of the patients in this disease. And as their share has grown over time, Remicade's share proportionately has declined by about the same amount.

And I indicated Cimzia as a relatively small player. You can see that here at only 2 percent share of the patients.

Q. So based on your experience in marketing at Centocor, what impact did the approval of Humira for Crohn's disease have on Remicade's sales for Crohn's disease?

A. Well, I think, based on this chart, it's had a rather significant impact. About 25 percent of the market that Remicade used to compete for by itself, Humira now competes for.

I think that the primary place that Humira has taken some of that share is in the use in new patients. When Humira was first introduced, the first types of patients that were treated with Humira were those who had already been treated with Remicade and it didn't work for whatever reason.

But what we see how is that actually about 60 percent of the patients being treated with Humira have never been treated with Remicade.

So these are these biologic naive patients that I spoke of earlier who are picking a drug, a biologic drug, for the first time.

Q. Now, let's go back to your first slide, if we can, to keep track of where we're going here. Well,

that's not your first slide. That's okay.

Actually, if you can describe what's on this slide.

A. Okay. So because there are a lot of drugs that we're going to be talking about this morning and a number of diseases, and they're not all the same diseases that the drugs treat, I thought I would just lay out who the primary competitors are in each of the disease states.

So we've just been talking about Crohn's disease. Remicade and Humira really are the only two major players in terms of the drugs that work and are approved in Crohn's disease.

I've put a checkmark under the small players. That's to describe Tysabri and Cimzia, the other two products. They each have, respectively, 5 percent or less of the market. And that's how I'm characterizing smaller players.

Q. So just to be clear, the green checks represent products that compete for the identified indication on the left?

A. Right, with an FDA-approved indication.

Q. Okay. We're going to use this scorecard to keep track as we go along today, correct?

A. I think it will just organize it and make it

all a little more clear.

Q. Okay. Good.

So if we can, let's go back to your first slide. Hopefully, we can do that.

All right. We're in business.

So we've just talked about the blue portion of your slide. Let's focus on the middle orange section.

A. Okay.

Q. There are three diseases there, and they're all a mouthful. Can you briefly describe what those diseases are?

A. I can. They all are autoimmune inflammatory diseases that attack different parts of the body. So in rheumatoid arthritis, the inflammation largely attacks the joints of the fingers and the hands. You've seen patients who have rheumatoid arthritis, their hands are sometimes curled; they'll have very large knuckles. It can also attack the joints of the knees.

Ankylosing spondylitis is a disease where the inflammation largely attacks the joints of the spine and the hip, and these patients oftentimes are hunched over. They have no movement of their head. They can't turn their head from side to side.

Psoriatic arthritis largely attacks the joints, like rheumatoid arthritis, as well as the skin.

Usually, there's a skin component, and they'll have psoriasis on their skin.

Q. Now, you've mentioned arthritis a couple of times. Are these diseases similar to the common form of arthritis called osteoarthritis?

A. They're not related at all.

Osteoarthritis is usually characterized by the -- the cartilage in between the joints erodes away, and the bone scrubs on bone.

So it's very painful, but it's very different. This is an inflammatory condition that causes swelling of the joints. It actually can cause loss or erosion of the bone itself.

Q. Now, before we leave this slide, it would be okay to refer to some of these diseases by their two-letter abbreviations or three-letter abbreviations, correct?

A. I think that will be easier, yes.

Q. Okay. Let's do that.

Do you have an understanding, based on your work at Centocor, as to how patients come to take products like Remicade and Humira for the treatment of these gastro -- or rheumatology diseases?

A. I do. In fact, I've prepared a chart that was similar to gastroenterology. And again, these patients

may be diagnosed as having rheumatoid arthritis by their primary care physician, or they could be diagnosed by a rheumatologist.

But, essentially, the way they're treated is, they'll first be given a drug that helps with the pain. That's an NSAID or a nonsteroidal anti-inflammatory. These are drugs like Naprosyn, like Celebrex, aspirin even, that really don't do anything to the underlying disease state. They just help with the pain that the patient feels.

If that's not enough, then the second step that would be taken would be a disease-modifying anti-rheumatic drug or a DMARD. These are drugs that actually do begin to work on the underlying inflammation of a disease. And a common example of a DMARD is Methotrexate, used very commonly.

And then the final -- if that doesn't work or the patient doesn't respond, the next step would be to go to a biologic.

Q. Let's focus on the middle box there, if we can there, the DMARDs. How are DMARDs taken?

A. DMARDs can either be given orally, by a pill, or they can sometimes be injected, if the patient's not able to take the pill.

Q. Is there a particular DMARD that's used more

often than others?

A. The most commonly used is Methotrexate, which is the example I've listed here.

Q. How is Methotrexate administered?

A. Most commonly, Methotrexate is given as a pill by mouth.

Q. Now, do patients ever use the biologic products in combination with a DMARD?

A. Patients are frequently administered both biologics and Methotrexate together.

Q. And why is that?

A. Well, I think for a couple of reasons. In most of the clinical studies that have ever been done with all of these products, Humira, Remicade, and Enbrel, those studies suggest that biologics actually work better when they're given in conjunction with Methotrexate than when given by themselves.

Q. So products like Remicade and Humira, when used with Methotrexate, actually work better than if used by themselves?

A. That's correct.

What does Remicade's label state about using Remicade with Methotrexate for treating RA?

A. For treating RA, the FDA-approved indication for Remicade suggested it should be given in combination

with Methotrexate.

Q. Now, that was just one of the three diseases that rheumatologists treat. The two others, PsA and AS, does Remicade's label indicate that the drug should be used with Methotrexate for treating those two rheumatology diseases?

A. No, it does not.

Q. And what does Remicade's label say about use with Methotrexate for treating the first column, the gastroenterology diseases, or the last column, the dermatology diseases?

A. Well, Methotrexate is not used at all as a drug in gastroenterology, so there's no use -- or requirement for the use of Methotrexate in the gastroenterology diseases.

And the same would be true for psoriasis. It's not required that Methotrexate be given with Remicade in psoriasis.

Q. So the only indication that Remicade's label says it should be used with Methotrexate is RA, correct?

A. That is correct.

Q. So let's focus on RA, if we can, for a moment. Do you have an understanding as to whether Remicade is always used with Methotrexate for treating RA?

A. In the majority of patients, Remicade is used

with Methotrexate, but, again, from our market research, we understand that about 15 to 20 percent of the time, Methotrexate is not given with Remicade. So Remicade is essentially given as a monotherapy.

Q. Is there a specific term that's used to refer to a drug in a manner that's different than the way it's described on its label?

A. We typically call that off-label use of a drug.

Q. Does Centocor promote Remicade for off-label use?

A. No, we do not. That's not allowed.

Q. Is off-label use by a doctor or patient illegal in any way?

A. It is, because physicians will always -- they'll always use their clinical judgment in determining the right way to prescribe a drug to each of their individual patients.

Q. Let me ask the question again.

A. Okay.

Q. Is off-label use by a doctor or patient illegal?

A. No, it's not.

Q. Is it unethical for a doctor to prescribe Remicade without Methotrexate for treating RA?

A. No, it is not. There are -- and there are reasons for that.

Methotrexate, because it is a disease-modifying drug, it's also a drug that in some patients -- not all patients will respond to all of these drugs.

And so there may be patients who have been on Methotrexate and didn't respond, and so it doesn't make sense to continue Methotrexate in that patient if they had no clinical response to it.

There are also patients who have adverse events with Methotrexate, or they can't tolerate it very well. And so in that case, the physician may decide he doesn't want to continue Methotrexate, and he wants to use Remicade by itself.

Essentially, the reason that we don't have a monotherapy claim for Remicade in rheumatoid arthritis is, we just never studied the drug that way.

So there's nothing unethical about using Remicade as a monotherapy.

Q. Still focusing just on RA, the first of the rheumatology diseases we identified before, do you have an understanding of what products Remicade competes with for the treatment of RA?

A. In rheumatoid arthritis, I would consider the

primary competitors Humira and Enbrel. Probably to a lesser degree, Orencia. And then there are a couple of other smaller products.

Q. Let's focus on Enbrel for a moment. What is Enbrel?

A. Enbrel is a product that also targets tumor necrosis factor, but it is not a monoclonal antibody. It's a fusion protein. So it's a different type of molecule.

Q. And when was Enbrel launched?

A. In 1998, the same year as Remicade.

Q. And how is Enbrel administered to a patient?

A. Enbrel is also self-administered by the patient through an injection.

Q. And you mentioned Enbrel as a competitor in RA, but you didn't mention them as a competitor in Crohn's disease, correct?

A. That's correct.

Q. Why is that?

A. One of the earlier studies that Enbrel did was in Crohn's disease, and they were doing it with the intent of getting an indication. And the study actually failed. So it showed that Enbrel was not effective in treating patients with Crohn's disease.

Q. I believe you also mentioned a drug called

Orencia; is that right?

A. Yes.

Q. What is Orencia?

A. Orencia is a different mechanism. It doesn't target tumor necrosis factor. It actually targets CTLA4 and is a drug that is -- it's administered by an IV infusion, much like Remicade.

Q. Let's just be clear. Is Orencia an anti-TNF antibody like Remicade and Humira?

A. It's not.

Q. And how is Orencia administered?

A. Through an intravenous infusion.

Q. Is the infusion of Orencia similar to the infusion of Remicade?

A. It's given in the same way, but it's given over a shorter period of time. Orencia infusions take about 30 minutes.

It's also given more often. A patient needs to get Orencia every four weeks, as opposed to Remicade, which is every eight weeks.

Q. Now, if you would please take a look at PX251, which should be in your book.

MR. MASLOWSKI: Joe, if we can put that up?

A. Okay.

Q. (By Mr. Maslowski) What is PX251?

A. PX251 is another example of the same type of study we were referencing earlier called PhysPulse. PhysPulse is a study that we do on a regular basis to monitor physicians' perceptions and attitudes about certain drugs and how they're using them.

This particular document is Wave 28 meaning the 28th successive wave of this research that we fielded, and this is now specifically looking at the disease, rheumatoid arthritis.

Q. Can you please turn to Page 21 of the exhibit?

A. Okay.

Q. Now, this looks like a pretty complicated chart. Can you please help us understand what is shown here?

A. I can. And maybe the first thing -- is this a laser pointer?

If you look at the legend at the bottom, you'll see what this is showing. This is the way products are used in what succession.

So first line, second line, third line, or fourth line. So it's just when and the progression of treatment a particular drug is being given.

If I look at the two products, Remicade and Humira -- I think I can illustrate what's going on here.

So the green boxes on the bottom, these two (indicating), in wave 28, for Humira --

Q. Hold on one second, Mr. Bazemore, if you wouldn't mind.

A. Yes.

Q. Which two --

A. Let's look at Remicade and Humira.

Q. And these two right there are Remicade (indicating), correct?

A. Those are Remicade. Wave 27 is 2007. Wave 28 is 2008, okay?

MR. MASLOWSKI: Thank you, Joe.

THE WITNESS: Yeah, that's better.

A. So, basically, what this is saying is, in the last wave of this research, which is what I'm showing, Wave 28, 22 percent of the total prescriptions for Remicade in this dark green box were -- it was -- it was the first time a biologic had been prescribed to that particular patient. So Remicade was being chosen as the first anti-TNF or first biologic.

Similarly, for Humira, 25 percent of their total use was also as a first-line drug.

So you can see that the two products are competing very effectively for first-line patients, and it accounts for roughly the same portion of their total

sales.

The other thing that you can see is that from Wave 27 to Wave 28, which is, again, 2007 versus 2008, the amount of first-line use actually increased both for Remicade and Humira.

So this suggests that there's more and more comfort or growing willingness to use both drugs as a first-line drug in the treatment of rheumatoid arthritis.

The other thing that it shows is that there are -- both green -- these lighter green bars (indicating), remember, that's second-line use for a patient who's going on to their second drug, as well as this white bar here (indicating), which is third-line use, patients who are going on the third drug. You see that amongst all three products.

So, basically, that means that as drugs don't work or patients are switching back and forth, they're really trying all of these products. They don't perceive them as being necessarily different in any way, just they keep -- they keep trying to find a drug that's going to work best for that patient.

So all three of these products are used as first-line, second-line, and third-line choices.

MR. MASLOWSKI: Joe, if you can back out.

Q. (By Mr. Maslowski) You mentioned the three products. The three products you're referring to are Enbrel, Remicade, and Humira; is that right?

A. That's correct. I'm primarily referring to the anti-TNFs at this point.

Q. And by the dark green and the light green boxes on the graph, that shows that those three products get the majority of the first- and second-line use, correct?

A. Almost all first- and second-line use is anti-TNF. I think in rheumatoid arthritis, that is regarded as being the gold standard class of treatment. And so you usually don't start use of other mechanisms until third and fourth line.

Q. Now, if patients and doctors preferred only the subcutaneous products or if that was the most important prescribing decision or factor, what would you expect to see in your chart?

A. Well, if subcutaneous was the most important factor and they all preferred subcutaneous use, I think you would not see first-line use of Remicade first.

The other thing I think you would not see is that light green bar, which is second-line use, because if they picked Enbrel first, they would all go to Humira as the second drug, being the only other subcu.

If they picked Humira first, they would all go to Enbrel. And so you really would see little to no second-line use of Remicade.

Q. So is the fact that there's a substantial number of numbers in the middle portion there for second-line use, does that indicate that some patients are going Enbrel, Remicade, Humira, or Humira, Remicade, Enbrel?

A. We had very detailed analysis that show that patients switch across all of these products. So patients who are originally treated with Enbrel will switch to both Remicade and Humira.

Patients who are originally treated with Humira will switch to both Enbrel and to Remicade. Patients who are originally treated with Remicade will switch to either of the subcu products.

So, yes, there is that phenomena occurring.

Q. So can you please summarize for us, just for RA, the level of competition among these products?

A. Well, I think you can see that they all compete for both first-line use, as well as for patients who are switching, which is the two large categories of patients that we talked about before.

Q. Do you have a slide that summarizes the level of competition among these products?

A. I do.

So this is a similar chart to the one that I showed before, which is looking at the percentages of patients that are treated with each of the various drugs.

Again, starting at the end of 2005, you can see that Remicade's share of the RA market was about 43-1/2 percent; Humira 16 or 17.

Over time, Humira's share has continued to increase. Now, at the end of 2008, about 21, 22 percent of patients are being treated with Humira compared to 30 percent of Remicade.

So you can see that number is down substantially compared to 2005.

Q. Have you added these products to what I call the scorecard before?

A. I have.

MR. MASLOWSKI: Can we go to that slide, please?

A. Okay. So -- and the reason I'm doing this is just to make it clear, because now this looks very different in rheumatoid arthritis.

You can see that the three major competitors still now here are Enbrel, Remicade, and Humira, the anti-TNF products. And together they account for about

85 percent of the total use of biologics in patients with rheumatoid arthritis.

Orencia, I'm categorizing as a major player, because they have more than 5 percent of the market. And then there are a couple of other smaller products that also are used here, like Kineret and Rituxan.

Q. (By Mr. Maslowski) Let's focus on those small products for a moment, Kineret and Rituxan.

A. Okay.

Q. How are they administered?

A. Kineret is given through a subcutaneous injection in the same way that Humira is given. And Rituxan is given through an intravenous infusion in the same that way that Remicade is given.

Q. So the small players on your chart include both subcutaneous products and IV products?

A. That's correct.

Q. Mr. Bazemore, in the end, what are Remicade's primary competitors in RA?

A. Our primary competitors in rheumatoid arthritis are Enbrel and Humira.

Q. Now, let's take a look at the other two rheumatology diseases, what I'll just call PsA and AS. Based on your work, do you have an understanding of what products Remicade competes with for those diseases?

A. So in psoriatic arthritis and ankylosing spondylitis, the two primary competitors are Humira and Enbrel.

Orencia --

Q. I'm sorry?

A. Orencia and the smaller players that are listed under rheumatoid arthritis are not indicated for those diseases.

Q. And do you have a slide that summarizes the level of competition there?

Just to back up one, we're talking about the last two in the orange box, correct, PsA and AS?

A. Yes, that's correct.

And so these are market share graphs. And I've only used 2008 here so that I can get them both on a single slide, but you can see that in both cases, Enbrel was approved in both of those disease states before either Remicade or Humira. And so Enbrel still holds the majority of market share.

But when you look at Humira and Remicade, you can see that Humira does have a substantial portion of both markets, almost a third. And, in fact, in ankylosing spondylitis, they're used more frequently than Remicade.

Q. Let's go back to your scorecard, if we can.

Can you tell us what you've done here?

A. So I'm just adding these two disease states, ankylosing spondylitis and psoriatic arthritis and showing the competitors.

And so, again, now you can start to see that there are differences amongst these products in terms of their overall indications.

Humira and Enbrel, as well as Remicade are all approved to treat these two disease states. Orencia and the other smaller players are not.

Q. Okay. Let's focus on all three of the rheumatology diseases, if we can, as a whole.

A. Okay.

Q. All three of the orange boxes there, RA, AS and PsA.

Again, are there particular features that doctors and patients look at when prescribing these drugs for those three diseases?

A. There are. And I would say it's probably no different than the ones that we discussed when we were talking about Crohn's disease. It is efficacy and safety first. They have to make sure that -- they want to make sure the drug is going to work in that particular patient, that it's safe for that patient.

Affordability, mechanism of action, the route

of administration, it's the same factors that we described before.

Q. Let's briefly take a look at them.

A. Okay.

Q. In terms of perceived safety, how do Remicade, Humira, and Enbrel compare in terms of treating the rheumatology diseases?

A. In rheumatology -- so, again, the labels, which is what the FDA has said we can actually promote to our physicians, the labels don't read that differently between the three products. They're all fairly similar.

And I think physicians all perceive that these products are safe amongst the patients that they choose to treat with them.

This is an area that's a little bit different than Crohn's. And there's always been a perception among rheumatologists that Humira -- or Enbrel and then later Humira are slightly more -- or they're more safe than Remicade. That is the perception and has been that way over time.

Q. So you mentioned that there's a slight difference in terms of safety perception. Can you explain a little bit further what that means or what it's based on?

A. Well, I think there are probably a couple of reasons. This is the -- the one RA specifically is the one disease where there's been direct competition between a subcutaneous product and an IV product since the beginning, because they were both approved in 1998 and 1999.

Going back to that, I think that Centocor always took a more conservative view towards our label, and there were certain safety adverse event signals that we saw that we chose to be more upfront with in terms of how we warned physicians.

And there's a section of a warning section on the label that's called a black box. It calls specific attention to those particular adverse events. And there were things that we put in our black box in agreement with the FDA, like risk of infections, risk of reactivation of tuberculosis.

Enbrel had some of the same types of warnings, but they chose not to put them -- and they agreed with FDA not to put them in the black box.

So there was some perception that there were differences between the products on some of these safety signals.

I think the other thing is that Remicade has been used more than any other anti-TNF in the market.

There have over 1.2 million patients treated with Remicade. It's the most used anti-TNF.

And so just by chance, if a new safety signal is going to emerge on one of these products, you'll usually see it first on Remicade, because it's been used in more patients than the others.

So many times, the signal would be seen first with Remicade. We would update our label. We would send a dear-doctor letter out telling the physician that we had updated the label.

And so it created a perception over time that there were safety issues associated with Remicade that may not have been the case with Enbrel or Humira.

If you look at our labels now, though, they are essentially all the same in terms of the way the language is constructed around safety. So there really aren't that many differences in the label.

And as -- and over time, as that's happened, you've seen the gap between Humira and Remicade or Enbrel and Remicade narrow in terms of the perception of safety.

Q. Now, we've been discussing perception of safety. Are you aware of any studies that show that Remicade is actually less safe than any of these products?

A. No. I think in order to do that, you would actually have to do a head-to-head study where you're studying them in the same patients and prove that one is safer than the other.

And to my knowledge, there have been no well-controlled head-to-head studies between the two products.

Q. So do doctors and patients actually view Remicade as an unsafe product?

A. No, absolutely not. I think they wouldn't use the product in a patient if they thought it was unsafe. And as I said before, it's been used in more patients than either Enbrel or Humira.

Q. In terms of perceived efficacy in treating the rheumatology diseases, are there any differences between Enbrel, Remicade, and Humira in terms of perceived perceptions?

A. Overall, if you look at the way rheumatologists would categorize these products, if you're thinking about -- like that chart I showed you earlier with the 8, 9, and 10, the degree to which they meet or satisfy efficacy, I think they would say that all three of these products are about the same. They don't perceive that any one is better or more superior to the other.

There are certain types of patients that they may think you would get better efficacy with Remicade; patients who may be heavier weight, because with Remicade, you can adjust the dose for the patient's weight; patients who have rapidly progressing disease where you would want a quick onset of action.

But other than that, if you look overall at efficacy, they don't perceive these products to be any different.

Q. And how important is mode of administration in treating the three rheumatology diseases?

A. It is a factor that they consider. As I said, with Crohn's, it's a factor amongst a number of other factors, and it depends on the individual patient.

Q. And how does the issue of cost affect the patient's decision with respect to rheumatology? Is it the same as with Crohn's?

A. It's the same as with Crohn's.

Q. And can dosing frequency also be a factor that's considered with respect to the rheumatology diseases?

A. It can, exactly.

Q. And can you explain generally how Remicade compares to Humira and Enbrel in terms of dosing frequency over the course of a year, for example?

A. Sure. So we've already described the fact that Enbrel and Humira both are given by themselves at home.

Enbrel is given either once or twice a week, depending upon whether the patient wants to divide the dose or give it all at once.

Humira is given every two weeks. They have an option of giving it every week if they're not using Methotrexate.

And Remicade is given every eight weeks as a starting dose.

Q. I'd like to switch gears for a minute.

As we've discussed, Remicade is an IV infusion product; Humira is a subcutaneous product.

Does Centocor have a subcutaneous anti-TNF product?

A. We do, yes.

Q. And what's it called?

A. The technical name is golimumab. It's marketed under the name Simponi.

Q. And it was just launched a month or two ago, correct?

A. About two months ago.

Q. And just to be clear, it's a monoclonal antibody like Remicade and Humira, correct?

A. That's correct.
Q. And it's a fully human monoclonal antibody?
A. It is.
Q. Does Centocor rely on the fact that Simponi is a fully human antibody when marketing the product?
A. No. In fact, the fact that it's fully human is featured very little at all in any of our promotional materials.
Q. Why is that?
A. Well, I think that physicians would only care about whether it's fully human to the extent that there is a benefit or some advantage to being fully human. And the FDA has expressly said that we can't connect being fully human to any clinical efficacy or safety advantage of the product.

And so if you can't say that that has an advantage in a patient, it's really hard to make that a core part of your promotional campaign for the drug.
Q. What indications is Simponi approved to treat?
A. Simponi is approved to treat all the indications on this slide in yellow, rheumatoid arthritis, ankylosis spondylitis, and psoriatic arthritis.
Q. And what features does Centocor rely on when marketing Simponi?

A. Well, Simponi, as I mentioned, it's a subcutaneous product like Humira, but there are a number of advantages, I think, which make it distinct.

One is it's dosed less frequently. So it's a product that's only given every four weeks as opposed to every two weeks.

We launched it with an auto injector that was designed specifically for patients with rheumatoid arthritis or rheumatic disease, so it's easy to activate.

Many RA patients don't have good dexterity with their fingers, and it's hard to activate. You have to press a syringe. This one you just squeeze the tube and it injects.

We've also found that the rate of -- the irritation that you see on the skin, injection site reactions, are fairly low with this drug. So it's a fairly comfortable drug for a patient to give.

So those are the features that make it unique in the market.

Q. Is Centocor going to stop selling Remicade now that it has Simponi?

A. Absolutely not. In fact, our business plans for this year and next year indicate that both Remicade and Simponi will continue to grow in use.

Q. How does Centocor market and sell Simponi?

A. We market and sell Simponi exactly the same way that we market and sell Remicade.

We look at those two large buckets of patients I described earlier, those who have never been on a biologic and those who have been treated and are switching for some reason, and we sell both Remicade and Simponi for both types of patients, and they each have their own distinct advantages.

We sell both, in fact, through the same sales force, because most physicians tend to use both IV and subcu products, and they'll choose what's right for an individual patient.

So we've not split a sales force and had one selling one and one sell the other.

Q. What types of patients does Centocor believe will be appropriate for Simponi?

A. We believe that both types, both the biologic naive patients as well as patients who have been treated previously with Remicade or another anti-TNF.

One of the studies that we did in our Phase 3 program for Simponi was to look at patients who had previously been treated with one or more other biologics and showed that Simponi worked very well in those patients.

And so we have data suggesting that it works even in a patient switching from another biologic.

Q. And how has Simponi fared on the market since it was launched?

A. Well, it's kind of early to say. It's only been out for two months. So some of the data that we get lags in terms of understanding. But I would say, so far, both Remicade and Simponi are exceeding our expectations for the year.

Q. Now, let's take a step back, and looking at the rheumatology diseases, all three of the orange boxes that are shown there, what impact did the approval of Humira have on Remicade's business for those three diseases?

A. Well, I think if you go back to the pie charts that I showed earlier, the impact was fairly significant. Humira has anywhere between 25 and 30 percent of the total share in each of those three markets.

If you look at where we compete directly, we compete for the first-line patient, we compete for the switching patient, and so we're all kind of competing for the same patients in each of those three disease states.

Q. Let's go back to your Slide 1, if we can, and

quickly talk about the last box, which is the dermatologists box.

A. Okay.

Q. Psoriasis, can you just briefly tell us what psoriasis is?

A. Psoriasis is also an autoimmune disease, like all the ones that we've been talking about. The manifestation of it is largely on the skin. So these are patients who will get plaques on the skin. They'll get scales. They'll get scabs.

Sometimes they form in areas where they can't be seen, and the patient can cover it up with their clothing. Sometimes it happens on the hands or the face or the neck, and it's really hard to expose -- or to keep from being exposed.

Q. And there are different levels of psoriasis, mild, moderate, severe, correct?

A. That's correct.

Q. And which of these levels is Remicade approved for?

A. Remicade is indicated to treat severe psoriasis.

Q. Is there anything that prevents a doctor from using Remicade to treat moderate psoriasis?

A. No. Again, I think that goes back to clinical

judgment. And, in fact, the designation of mild, moderate, severe is largely a -- it's a -- it's a score that's done by the physician, and it's fairly subjective.

Some patients, mild, moderate, and severe is usually determined by how much of their body surface is covered with the disease. But a patient can have a relatively small amount of disease but have it somewhere where it's visibly, like on the face or the neck, and he may consider that patient as having severe disease.

So there's nothing that would prevent a physician from using Remicade in a moderate patient.

Q. Can we go to your next slide, please? Can you briefly tell us what's shown here?

A. This is a similar example of the way that drugs are used in succession to treat patients with psoriasis, very similar to the other therapeutic areas that we talked about.

So usually what will happen is, with a parent who comes in, they're initially diagnosed. They may -- a physician may try to use a topical treatment. This could be a topical steroid or some other type of cream. If that doesn't work, they may be given light phototherapy. This is kind of the equivalent of standing in a tanning bed to see if the UV light

sometimes will make the psoriasis go away.
If not, they may prescribe systemic drugs, some of the same types of products that we've talked about before, like Methotrexate and steroids.

And if those don't work -- and they don't always go through all of these. Sometimes they'll try one and then go directly to the biologic class. But that would ultimately be where they ended up, if they didn't respond to the other drugs.

Q. Now, have you added psoriasis to your chart summarizing the competition?

A. I have.

Q. Can you please explain what is shown here?

A. So this chart, again, just goes back and says -- shows who are the major competitors that compete for this space.

The majority market share in psoriasis is, again, the same three drugs, Remicade, Enbrel, and Humira. There are a couple of other smaller players, namely, Amiveve. There was another product that was just withdrawn by the FDA -- or the company removed it because of FDA concerns over safety named Raptiva.

Q. Now, Remicade has approval for severe psoriasis, and Humira and Enbrel are approved for moderate to severe psoriasis, correct?

A. That's correct.

Q. Does Remicade, nonetheless, compete with Humira and Enbrel for the treatment of psoriasis?

A. Absolutely, it does.

Q. Let's focus on just one of the product features for a moment.

Is mode of administration important to dermatologists when prescribing biologics for psoriasis?

A. It is important. And I would say the mode of administration, whether it's subcu or IV is probably more important to the dermatologist than it is to any of the other specialties that we've talked about.

Q. Well, does that mean that dermatologists won't use Remicade?

A. Not at all. There -- there are other ways that they can prescribe Remicade. What it means is they -- many dermatologists just choose not no infuse Remicade in their offices for different reasons. But they can always write a prescription for Remicade and have it given by another specialty, like a rheumatologist, they can send them to a hospital to have Remicade administered, or they can send him to some other type of infusion center and have it administered. So they don't have to give it in their office for a patient to get it.

Q. So to finish up in the dermatology area, can you please describe what impact the approval of Humira in psoriasis had on Remicade's business in psoriasis?

A. I think it had a fairly significant impact. Most of the patients that Remicade competes for in psoriasis are patients who have already failed Enbrel. Enbrel is by far and away the drug used most commonly in psoriasis.

It used to be, before Humira was approved, that some of those patients, if they failed Enbrel or it didn't work them, they would try Remicade as the next step, because it's such a disabling type of disease.

With the introduction of Humira, now there's another product that patients can use before they come to Remicade. And so it's created a position for Remicade where we're more of a niche product, probably third-line use in most cases, as opposed to second-line use with Humira being introduced.

Q. And I think we've made our way through this scorecard completely, correct?

A. That's correct.

Q. Let's take a step back and look at it as a whole.

Is Humira a competitor of Remicade in every single indication that's shown on that chart?

A. I think if you'll look at the checks, you'll see that Humira's probably the closest competitor to Remicade in all the indications where we compete.

Q. And has Humira's approval in each of those indications impacted Remicade's business for each of those indications?

A. It has, yes.

MR. MASLOWSKI: I pass the witness.

THE COURT: All right. Ladies and Gentlemen, we'll take our morning break. Be ready to come back in the courtroom at 10:30.

Remember my instruction about not discussing the case. You may leave the courtroom.

COURT SECURITY OFFICER: All rise.

(Jury out.)

THE COURT: All right. Court's in recess until 10:30.

(Recess.)

COURT SECURITY OFFICER: All rise.

(Jury in.)

THE COURT: Please be seated.

Cross-examination.

MR. LEE: May I proceed, Your Honor?

THE COURT: Please.

CROSS-EXAMINATION

BY MR. LEE:

Q. Good morning, Mr. Bazemore.

A. Good morning.

Q. Mr. Bazemore, I want to ask you a favor. I want you to slow down a little bit so that we can make it easier for the reporter.

Can you do that?

A. I will.

Q. Okay. Now, you were here during the opening argument, were you not?

A. I was.

Q. And you heard Ms. Elderkin say that February 1994 was a very key date for this jury, correct?

A. Correct.

Q. You didn't join Centocor until 2002, did you?

A. That's correct.

Q. So you actually can't help the jury with what was going on at Centocor in 1994, correct?

A. That's correct.

Q. Or at anytime before 2002, correct?

A. Only from historical knowledge that was passed on to me.

Q. But not from your own personal knowledge, correct?

A. That's correct.

Q. Now, you do have a degree from Georgia in biochemistry, correct?

A. That's correct.

Q. Now, I want to ask you the same questions I've asked every Centocor witness.

Have you ever made a fully human anti-TNF-alpha antibody?

A. I have not.

Q. Chimeric?

A. I have not.

Q. A mouse?

A. No.

Q. Any?

A. No.

Q. Never?

A. Never.

Q. Have you ever read the '775 patent?

A. I have not.

Q. Not at all?

A. No.

Q. Now, you agree with me that patients -- withdraw.

You had a bunch of slides up on the screen that talked about the competition, correct?

A. That's correct.

Q. And you talked about competitors, correct?
A. Correct.
Q. You agree with me that competition is a good thing, isn't it?
A. Yes.
Q. Having competitors is a good thing, correct?
A. Having multiple companies promoting this class of product, which brings benefit to patients is a good thing.
Q. Having patient choice is a good thing, correct?
A. Sure, because not all these drugs work in every individual patient.
Q. Having physician choice is a good thing, correct?
A. Correct.
Q. And the more choices there are, the more products there are on the market, the more choices that physicians and patients have, correct?
A. Correct. In a disease like this, not every drug works. That is correct.
Q. Right. Now, I want to ask just one question quickly about Simponi.
You told Centocor's counsel that Simponi is a fully human antibody, correct?

A. It is.
Q. It's administered subcutaneously, correct?
A. That's correct.
Q. But you said it doesn't really make a difference whether it's chimeric or fully human, correct?
A. I said that the FDA doesn't let us promote any advantages or benefits of being fully human.
Q. So if that's true, when you wanted to have a subcutaneous product, why didn't you just take Remicade and get a subcutaneous product approved?
A. I suppose that could have been done. I'm not responsible for the clinical decisions.
Q. Right. So when Centocor decided that it wanted to have a subcutaneous product, it developed a fully human antibody rather than using a chimeric, correct?
A. I think the decision for why we chose to develop golimumab was the dosing frequency and the fact that it could be given every four weeks. That was an advantage.
Q. My question, sir, was, when Centocor decided to develop a subcutaneous product, it chose to develop a fully human antibody, correct?
A. That's correct.

Q. And not a chimeric, correct?
A. That's correct.
Q. And you can't help the jury as to why that decision was made, correct?
A. Well, again, I think part of the reason that that was done was that golimumab was a molecule that could be given every four weeks, which is much less frequent than any of the other subcutaneous products on the market.
Q. Okay. Now, let's talk about what happened to the market after Humira entered the market, okay?
A. Okay.
Q. By this time, you were at Centocor, correct?
A. That's correct.
Q. And, in fact, you arrived just about the time that Humira arrived, correct?
A. Humira came on the market just about a year after I arrived at Centocor.
Q. And so the jury understands, what happened was, after Humira came on the market, the market actually grew in size, didn't it?
A. That is correct. The market was already growing in size.
Q. Right. And when Humira came on, it grew even further, correct?

A. It did continue to grow.

Q. And, in fact, what happened is, as the market grew, Centocor sales of Remicade had yet gotten larger every single year since Humira came on the market, correct?

A. That's true. That was happening before and after Humira was launched.

Q. All right. Let's bring up PX425, and it's in the notebook before you at Tab 13, if that's easier for you.

A. Tab 13?

Q. Yes. But, Mr. Bazemore, I'll also put it on the screen.

I want to be sure that everyone understands just what's happened to Centocor's sales of Remicade since Humira entered the market.

MR. LEE: And if we could highlight the sales numbers for 2003/2004.

Right. Right across -- all the way across to 2008, if we could.

Q. (By Mr. Lee) Do you see that first line?

A. I do.

Q. And it's describing Remicade sales in the U.S., correct?

A. That's correct.

Q. So you were 1.4 billion or so in 2003, correct?

A. That is correct.

Q. And you grew to 1.8 billion, correct?

A. That's correct.

Q. Then you grew to 2.065 billion, correct?

A. Correct.

Q. Then to 2.35 billion, correct?

A. That's correct.

Q. 2.5 billion, correct?

A. Correct.

Q. And then to 2.8 billion?

A. Correct.

Q. So the sales of Remicade have doubled since Humira entered the market, correct?

A. That is correct. But that wouldn't explain the reasons --

Q. Is that correct, sir?

A. That is correct.

Q. So your real complaint isn't with your sales. It's that your market share has gotten smaller, correct.

A. That is correct.

Q. Right. Now, and as your market share got smaller, what Centocor decided to do was to sue Abbott, correct?

A. I don't think those two things are related.
Q. You think they are totally unrelated?
A. I don't think they are related to market share.
Q. Okay. Now, let's talk about some of the testimony you gave about Remicade and Humira.
Now, you said Remicade is administered intravenously, correct?
A. That is correct.
Q. Now, just so we have in mind what that requires -- we're not going to do it here -- but this is the rig that's required when you go into a doctor's office to get it intravenously, correct?
A. For the most part, yes.
Q. And there's usually what's called a crash cart sitting next to it, correct?
A. Not next to it. In the facility.
Q. Right. And the crash cart's in case something bad happens when you're getting the IV, correct?
A. That is the requirement for any infusion center. It has nothing to do with Remicade.
To be able to give an infusion of any sort, that's one of the requirements the center has to have.
Q. Right. Now, let me show you, if I could, what the patient gets for Humira.

This is it, right?

A. That's one version. That's the autoinjector.

Q. Right. And so instead of this whole rig and the crash cart and going to the doctor's office for a few hours, the Humira patient shoots, if the patient chose this or the physician has chosen this, they take this at home, inject themselves, and be done with it, correct?

A. That's correct.

Q. Now, you said -- I think I got it right -- that the Humira patient has to find a vein to inject. They don't do that.

A. No. That's for Remicade.

Q. Right. In fact, for Humira, the patient injects themselves in the stomach, and they don't have to find a vein, which makes it easier yet, correct?

A. That is correct. They inject themselves.

Q. Now, you talked about preferences for different types of administration, correct?

A. Yes.

Q. You talked about perceptions of safety, correct?

A. Correct.

Q. I want to look with you at a few documents that describe actually what Centocor has said itself

about these issues.

Turn, if you would, to Tab 1, which is PX695.

MR. LEE: Which is in evidence, Your Honor.

If I could have PX695, Page 28 on the screen.

Q. (By Mr. Lee) Now, just so we're clear, this is a Centocor document, correct?

A. It appears so, yes.

Q. It's dated January 18th, 2007, correct?

A. That's correct.

Q. And Centocor says: Each mode of administration carries difficulties that influence patient preference, correct?

A. Correct.

Q. And then for injection preference, it says 63 percent, correct?

A. On the slide, that's what it says.

Q. On this Centocor slide, that's what it says, correct?

A. I'm saying on the Centocor slide, because the source of the data is the Annals of the Rheumatic Diseases, so we're just reproducing data.

Q. Okay. And that's the data that you reproduced for your internal use, correct?

A. No. Actually, we field our own market research directly with patients and physicians to understand perceptions.

This is a secondary source from a study that was fielded by the Annals of the Rheumatic Diseases.

Q. Right. Someone who's independent, correct?

A. Correct.

Q. Who has no interest in coloring the conditions in the market, correct?

A. That's true. You could argue we have no interest in coloring divisions. If it affects our marketing strategy, we would want it to be accurate.

Q. Mr. Bazemore, my question was, the Annals of the Rheumatic Diseases, they have no bias, prejudice, or otherwise, correct?

A. I assume not.

Q. Right. And their determination or their finding, which you've reproduced in your slide, is 63 percent prefer subcutaneous, correct?

A. Correct.

Q. And at that time, that would be Humira, in 2007, correct?

A. Correct.

Q. And 21 percent prefer IV, correct?

A. Correct.

Q. Now, this isn't the only time there's a Centocor document that talks about how many people prefer subcutaneous, correct?

Turn to PX257. Do you have it?

A. Which tab is that?

Q. Tab 2.

MR. LEE: Also in evidence, Your Honor. And could I have Page 49 from this January 30, 2008 document on the screen?

Q. (By Mr. Lee) Do you have that before you?

A. I do, yes.

Q. Now, it says rheums. You know what that is, don't you?

A. Rheumatologists.

Q. Right. Rheums report that 67 percent of their patients prefer subcutaneous injection as a method of administration versus 21 percent that prefer IV, correct?

A. Correct.

Q. Now, this is Centocor's own data, correct?

A. Correct.

Q. And it's consistent with the Annals data that I just showed you a minute ago, correct?

A. In a different disease state.

Q. Right. But 67 percent, correct?

And for those people, those folks in that 67 percent who preferred the subcutaneous in 2008, the product available to them was Humira, correct?

A. As well as etanercept.

Q. Now, let's talk about safety. You talked a little bit about safety, and you talked quite a bit about what the FDA will allow you to say and not to say, correct?

A. That's correct.

Q. But you know that there are perceptions of safety on the part of patients, correct?

A. We don't track the patients' perceptions as much as we track the physicians' perceptions.

Q. Fair enough. So you track the physicians' perceptions of safety because they are important, correct?

A. That is correct.

Q. Now, you know that one of the concerns is that chimeric antibodies can cause an allergic response in humans, do you not?

A. All antibodies can cause an allergic response in humans.

Q. But chimeric in particular can cause greater immune responses than human, correct?

A. The FDA doesn't allow us to talk about

differences in terms of the antibody response between the products.

Q. Well, let's see what Centocor itself said.

MR. LEE: Could I have DX67, which is in evidence, which is --

A. Tab number?

Q. (By Mr. Lee) Yes. I'm sorry. Tab No. 15.

Do you have it before you? Tell me when you get there.

A. Okay.

Q. Now, you see this document, which is authorized by John Ghrayeb. You know who he is?

A. I do.

Q. The jury heard from him yesterday, correct?

A. Correct.

Q. Let's turn to Page 4, and let's see what the Centocor internal documents say.

Human antibody program, now you know that refers to Simponi, correct?

A. That is correct.

Q. And that refers to something that was started in 1997, correct?

A. Correct.

Q. Now, one of the major issues, real or perceived, of chimeric or humanized monoclonal

antibodies, is the potential for immunogenicity that could limit their chronic use.

In theory, totally human monoclonal antibodies should result in elimination of immune response, real or perceived.

Have I read that correctly?

A. That is what this document says.

Q. That's Dr. Ghrayeb, right?

A. Yes.

Q. The head of the project is saying it.

A. He's saying that, in theory, a theory which has never panned out, which is why the FDA doesn't allow us to promote differences on immunogenicity.

Q. Well, let's see what Centocor's own documents say about how it panned out.

MR. LEE: Could we have PX254?

Q. (By Mr. Lee) Which is Tab 3 in your notebook again.

This is a PhysianPulse report, correct?

A. Uh-huh.

Q. Do you have it?

A. I do.

Q. Okay. And if we could turn to Page 36.

Now, there's a complicated chart here, but I'm going to ask you about the conclusions that are reported

by Centocor.

Now, this is a document that Centocor generated internally, correct?

A. That's correct.

Q. And it generated it for its own use, correct?

A. We generate this in coordination with a market research vendor, yes.

Q. And it's important that it be truthful and accurate, because you're relying upon the data to make business decisions, correct?

A. That is correct.

Q. So at the top of Page 36, what does it say? Remicade's mean performance rating on overall safety has declined significantly in this wave compared to the last wave.

Have I read that correctly?

A. You have.

Q. And then if I go to the bottom underneath the charts, the conclusion from the charts: Enbrel and Humira continue to be rated significantly higher than all other therapies on overall safety.

Remicade continues to be perceived as significantly safer than Orencia and Rituxan based on mean ratings, correct?

A. That's what it says, yes.

Q. And that's what you reported internally, correct?

A. That is correct.

Q. Now, that's not the only time that that was reported.

Turn to Tab 4 to DX526, another Centocor internal document.

Tell me when you get there.

A. Which page?

Q. Tab 4 first, and then I'm going to go to Page 53, Mr. Bazemore.

Do you have that before you?

A. May I make one comment on the previous slide before we go to this one?

Q. Sure.

A. So if you can back up to the previous slide, I'd just like to comment a moment further, because one of the points that you made is --

Q. Your counsel will have an opportunity to ask you additional questions. I thought you had a comment on the slide I was showing you, but, look, we'll go back.

What's the comment you would like to make?

A. The comment I would like to make is to the title. You're right. It does refer to the fact that

the overall safety for Remicade declined. I'll just note that overall safety during the period that we're talking about here for all products declined, not just Remicade, over that period.

Q. Okay.

A. And I'll also comment on the data. This is 2006.

THE COURT: Now, wait a minute. We're going to stop the commenting. We've got some time limits. You just need to answer the question. We're going to proceed by question and answer, okay?

THE WITNESS: Okay.

Q. (By Mr. Lee) Now, let's go back to 256 (sic), Page 53.

A. Okay. I'm there.

Q. Do you have it before you?

A. I do.

Q. And this is a 2007 document at the bottom, correct?

A. Actually, the date is different from the title. I think it may be an auto-correct date. The title on the first page says December 2005.

Q. Right. Whichever it is, the title of the document says: Major Drawbacks to Remicade Use Are IV Infusions and Safety Concerns, correct?

A. That is correct.

Q. And then what you report internally is: Safety concerns cited for Remicade are infusion reactions and infrequent but potentially serious infections, TB, tumors, correct?

A. That is correct. And those are risks for all products.

Q. Okay. I just asked you what it said. That's what it said, correct?

A. It does.

Q. And TB is tuberculosis, correct?

A. Correct.

Q. Now, you mentioned Exhibit 261, which is at Tab 5, and you actually testified about 261 during your direct testimony today, did you not?

A. I did.

Q. Now, this one is dated February 3, 2009, correct?

A. Correct.

Q. So it's just a few months ago, correct?

A. Yes.

Q. And you asked the jury to look at Page 9.

Let's look at Page 20. Do you have Page 20 before you?

A. I do, yes.

Q. And Page 20 says: The percentage of MDs considering safety/side effects as a barrier to usage of Remicade is significantly greater compared to Humira.

Have I read that correctly?

A. Yes.

Q. And that was your finding earlier this year, correct?

A. That is correct. That's what the chart shows.

Q. Right. And all of the findings I've just reviewed on these six or seven internal documents were accurate reports of the data that you had received, correct?

A. That is correct.

Q. Now, let's talk about the markets a little bit just briefly, each of the markets that you've addressed. One which you discussed in the middle was called -- in the middle of your chart was the rheumatology diseases, correct?

A. That is correct.

Q. And you described a class of drugs called DMARDs, D-M-A-R-D-S, correct?

A. Yes.

Q. One of the DMARDs is Methotrexate, correct?

A. Correct.

Q. Now, Methotrexate is a really, really powerful

drug, isn't it?

A. It is an immune-suppressing drug like the anti-TNFs, yes. So that would make it a powerful drug.

Q. And it's used to treat things like cancer, is it not?

A. That was how it was introduced into the market.

Q. Right. Because it kills cells, correct?

A. Suppresses the body's immune system.

Q. Right. And it can have significant side effects, correct?

A. It can.

Q. And they can be pretty miserable side effects, correct?

A. Correct.

Q. Now, for rheumatoid arthritis, the label says Remicade has to be used with Methotrexate, correct?

A. That is the label.

Q. But for Humira, the label says you don't have to use it with Methotrexate, correct?

A. That is correct.

Q. So patients want a choice, and if they don't want to use this powerful, cancer-killing drug, Remicade would be the label that they would go to, correct?

A. I'm sorry. Repeat the question.

Q. Sure.

If I had a patient who didn't want to take Methotrexate --

A. Uh-huh.

Q. Do you have that in mind?

A. Yes.

Q. Then -- and they wanted to comply with the FDA label.

Do you have that in mind?

A. Yes.

Q. Then they would want Humira, correct?

A. I thought -- because you said Remicade the first time.

Yes.

Q. Okay.

A. Humira might be a drug that they would choose if they couldn't tolerate --

Q. Rather than Remicade, correct?

A. That's true, although physicians do use Remicade without Methotrexate.

Q. Yeah, but that's what you call off-label use, correct?

A. Correct.

Q. And you would never promote that, correct?

A. We can't promote it that way.

Q. It would be illegal, correct?
A. That's correct.
Q. Okay. Now, let's talk about on-label use. If a patient wants on-label use without Methotrexate, Humira is the choice, correct?
A. Humira or Enbrel either one are both indicated that way.
Q. Right. Enbrel, similarly, doesn't require the use of Methotrexate, correct?
A. That's correct.
Q. And you agree that having that patient choice, that choice of being able to take the drug without this powerful drug, is a good thing, correct?
A. If that were the only factor driving the decision, that would be an important consideration.
Q. And until Humira came on the marketplace, patients didn't have that choice, did they?
A. No. They had that choice with Enbrel. And as I said, they already wrote Remicade off-label in some cases.
Q. So until Humira and Enbrel came on the marketplace, patients didn't have that choice, correct?
A. Correct.
Q. Now, let's talk about dermatology briefly.
Now, you said that Remicade is approved for

severe psoriasis, correct?

A. That's right.

Q. Humira is promoted for moderate psoriasis, correct?

A. That is correct.

Q. So they overlap a little bit, correct?

A. That's right.

Q. But for Remicade, if you want to use it for severe psoriasis, you still need to go a doctor's office and get hooked up to this (indicates), don't you?

A. You would, even a dermatologist's office, or they would send you somewhere else for the infusion.

Q. Now, the truth of the matter is there are a lot of barriers to having dermatologists' offices that have this rig all hooked up, aren't there?

A. That's true. In fact, I've already testified that dermatologists were more reluctant to put in-office infusions in their offices than the other specialties.

Q. Yeah. And the reason you know that is, you've actually studied that at Centocor. You had someone evaluate that for you, correct?

A. That's right.

Q. And if you'd turn to Tab 9, which is DX519.

A. Okay.

Q. Do you have that before you?

A. I do.

Q. Now, DX519 is a study that you hired a consulting firm to do for Centocor, correct?

A. That's right.

Q. And one of the things you wanted to find out is what are the barriers for people using Remicade, correct?

A. That's right.

Q. And they came back and told you Remicade has some real disadvantages compared to Humira, for instance, which is administered at home subcutaneously, correct?

A. Is there a specific page that you're asking me about?

Q. Page 35.

And what the findings were, on Page 35, are the following: Most physicians believe that in-office infusion centers are beyond the scope of the typical dermatology practice.

Do you see that?

A. I do.

Q. Now, an infusion center is what's required to take Remicade, correct?

A. That is correct.

Q. And the reasons are, the need for a separate

infusion area, correct?

A. That's correct.

Q. If we skip down to the bottom: The cost of/need to store infusion paraphernalia, correct?

A. Correct.

Q. If you go to the next slide.

The requirement of certification for advanced life-saving. That refers to the crash cart, correct?

A. Correct.

Q. The hours needed to infuse, correct?

A. Uh-huh. That's correct.

Q. The necessity of a nurse, correct?

A. Right, which ties back to the first of having someone certified in advanced life-saving.

Q. Fair enough.

And all of these factors result in self-administered subcutaneous administration being preferred by most dermatology patients, correct?

A. Most dermatologists choose not to put infusion facilities in their office.

Q. And without Humira, at least before a couple of months ago, a patient's choice would be to go to the office, go through all this, get hooked up and get Remicade, correct?

Is that right?

A. Correct.

Q. Okay. Now, just a couple of questions about the gastroenterology market.

You also said that in this market, Remicade and Humira compete, correct?

A. That's correct.

Q. Now, it's true, is it not, that there are some patients where Remicade just doesn't work? Correct?

A. There are some patients that all of the products don't work. That's correct.

Q. Right. They're called Remicade-failure patients, correct?

A. True.

Q. The fact of the matter is, many of the sales of Humira have been made, for instance, in the area of Crohn's disease, for patients who took Remicade and it failed, correct?

A. That is true, particularly when Humira was first approved.

Q. And you described the very and really difficult symptoms and painful aspects of Crohn's disease, did you not?

A. I did.

Q. So before Humira came on the market, those folks for whom Remicade didn't work were left without

anything, weren't they?

A. Some of them would -- after cycling off, would come back on to Remicade, and they actually responded.

Q. And some didn't, correct?

A. And some didn't.

Q. And Humira is what has made it possible for those folks, right? For those folks to have a relief from the symptom and a relief from the disease, correct?

A. That's true.

Q. Now, it's true, is it not, that -- let me go to your fully human antibody product that you discussed --

A. Okay.

Q. -- with me just a few minutes ago.

It was approved on May 19th, 2009, correct?

A. It was approved in April of 2009.

Q. Okay. Fair enough.

And you brought it to market, correct?

A. True.

Q. And you told us that it's doing well, correct?

A. It's hard to tell yet, but it seems to be.

Q. And you said Remicade's still doing well, correct?

A. That is right.

Q. Now, Centocor spent over $300 million in

developing that fully human antibody, didn't they?

A. That sounds about right. I don't know the actual number.

Q. All right. Well, look at DX531, which is Tab 12, and let's turn to Page 39.

This is another -- let me stop on the cover page.

A. Okay.

Q. So the jury knows, on the cover page, there's a reference to CNTO148. That's Simponi, correct?

A. Correct.

Q. Turn, if you would now, to Page 39.

A. Okay.

Q. CNTO148, Cost Estimates, Overview of Buy-In, Initial and Short-Term Ongoing.

There's an estimate of costs through 2004 of 146 million, correct?

A. That's right.

Q. And then forecast for 2005 and 2006 of approximately another 158 million, correct?

A. Correct.

Q. That totals over 300 million, correct?

A. Uh-huh.

Q. You have to give an audible answer for the reporter.

A. Yes.

Q. Now, if I were to have Simponi here, it would look a lot like this, wouldn't it?

A. It would look fairly similar. It's in an autoinjector and a pre-filled syringe.

Q. Right. Rather than having a full rig to be hooked up to, Simponi looks like a single product with a syringe inside that the patient can use, correct?

A. That's correct.

Q. Now, sir, you told us earlier today about the competition in all the different markets, and I think you told the jury that Humira's products, which are subcutaneous, correct?

A. That's correct.

Q. Compete directly with the products of Remicade, which are IV, correct?

A. That's right.

Q. But isn't it true that Johnson & Johnson just told its shareholders a few months ago that Simponi is going to be in the subcutaneous market where you don't compete today?

A. I think I've already testified that there are a portion of patients who prefer subcutaneous that Remicade -- if that's their absolute preference that Remicade wouldn't compete.

THE COURT: Listen to his question.

MR. LEE: Right.

THE COURT: He asked you a question about whether or not you knew that Johnson & Johnson had told their shareholders something.

Are you aware of an annual report or some publication that they released about this? That's the question.

A. I am aware of the statement.

Q. (By Mr. Lee) Right. Let's look at the statement, which is in evidence, Defendant's Exhibit 877, which is at Tab 10, Page 4.

And I'm going to blow up a paragraph.

MR. LEE: Could we blow up the fourth paragraph from the bottom, beginning with Simponi, and highlight it?

Q. (By Mr. Lee) Now, you've seen this report before, have you not?

A. I have.

Q. And this is a discussion with analysts in the marketplace about just what Simponi is going to be, correct?

A. That's correct.

Q. And it describes Simponi as subcutaneous, correct?

A. Correct.
Q. And you know Remicade is not, correct?
A. That's right.
Q. And so what the stockholders want to know is, are these two, subcutaneous and IV, going to compete, correct?
A. I assume so.
Q. All right. And today, you have talked to us all about that competition between subcutaneous and IV, have you not?
A. I have.
Q. All right. Let's go to Page 5 and see what Johnson & Johnson said to the marketplace.
Sheri McCoy, do you know who she is?
A. I do, yes.
Q. She's the Worldwide Chairman of Johnson & Johnson's pharmaceutical groups, correct?
A. That's correct.
Q. And what does she say?
MR. LEE: Could I have the sentence that begins: Where we see the opportunity?
Let's blow up the paragraph and highlight the sentence.
Q. (By Mr. Lee) Where we see the opportunity for Simponi is to go into the subcu market, where we don't

compete today, correct?

A. I see that.

Q. So you spent an hour and 20 minutes today trying to convince us that there is direct, head-to-head competition in the subcu market, correct?

A. That's correct, there is.

Q. But your Worldwide Chairman told the marketplace the opposite just a few weeks ago, correct?

A. That's the gist of her statement. I would like to explain, if I could.

Q. No need.

MR. LEE: Thank you, Your Honor.

THE COURT: Redirect.

MR. MASLOWSKI: Joe, can we please have DX877 back up?

REDIRECT EXAMINATION

BY MR. MASLOWSKI:

Q. Now, Mr. Bazemore, you were just asked a question about this exhibit; isn't that right?

A. That's right.

Q. And particular statements by Sheri McCoy, correct?

A. That's correct.

MR. MASLOWSKI: Joe, if you can please go to Page 5 and highlight the question -- just highlight

the answer, Ms. McCoy's answer near the bottom, the fourth paragraph up.

Q. (By Mr. Maslowski) Now, you've reviewed this transcript before today, correct?

A. I have, yes.

Q. And you were here for Mr. Lee's opening statement, correct?

A. I was.

Q. And during his opening statement, he pointed the jury to the same sentence that he pointed you to, correct?

A. That's correct.

Q. Take a look at the last sentence of Ms. McCoy's answer, if you would.

MR. MASLOWSKI: Joe, can you highlight that, please?

Q. (By Mr. Maslowski) Have you had a chance to review this entire answer, including the last sentence?

A. I have.

Q. And taking the whole answer in context, what does it tell you about the way Remicade and Humira compete in this business?

A. Well, I think it's consistent with my previous testimony. And this further elaborates that it lets us compete more directly with a competitive set in that

space.

I've said before that there are patients who clearly have a preference for subcutaneous products. I think the data that I cited shows that -- the other data that we just described shows that.

In the cases where everything else is equal, and this is an important consideration, because everything else isn't always equal -- but if everything else is equal between products, some patients will opt for a subcutaneous product over an intravenously administered product.

So having a product for those patients is an important thing for us as a customer, but that doesn't mean that they are clearly in defined markets, as I've shown before in the slides that we just showed.

There are some patients who don't have a strong preference for one or the other, and other factors are more important to them than the form of administration.

Q. Now, with respect to this last sentence, she says at the very end: Certain -- I understand this is a transcription error -- but certain anti-TNFs will be up after that as well as going more directly with the competitive set in that space.

Can you focus specifically on the last

sentence and tell us what you understand that to mean?

A. And I understand -- my understanding of that is these are patients who may have already failed one other TNF, which is the second of the populations of patients that I described as being important. Those who have already been treated with one anti-TNF, their physician is trying to help them understand which is the best for the next drug.

And in this case, we did a study specifically in this patient population, those who have previously been treated with one biologic, and showed that Simponi works very well in that patient population.

So that's a study that will let us compete more effectively for that type of patient, someone who may have already failed Humira, who may have already failed Remicade or Enbrel.

Q. Now, once you've had the opportunity to consider Ms. McCoy's full answer, is she telling the investing public Remicade does not compete at all with subcutaneous products?

A. I think what she's telling the public here -- the answer to that question is no.

I think what she's telling the public is, that with both products, we can more specifically address all the patient needs across these disease states than we

could with any one single product.

Q. Now, let's switch gears for a second.

A couple of times Mr. Lee made reference to a crash cart. Do you recall that?

A. I do, yes.

Q. And he indicated that's a requirement for an infusion of Remicade, correct?

A. It's a requirement for having an infusion facility for any purpose, infusing any kind of drug, whether it be Remicade or anything else.

Q. So it's a requirement not just for anti-TNF infusion drugs; it's any infusion drugs, correct?

A. That's correct.

Q. Now, do you have an understanding of why the crash cart would be present for the infusion?

A. Well, because patients who are infused with particular drugs can oftentimes have a severe injection -- or infusion reaction that can have an anaphylactic-type reaction.

It's very mild -- or it's very rare. It rarely occurs, but in the event that it would happen, you would want to be prepared to be able to deal with it. And that's part of the reason that it's an advantage of having an infusion. You're there with a nurse and a physician should that happen.

Q. You mentioned an anaphylactic response. Just briefly, what is that?

A. An anaphylactic response is just a severe allergic reaction. Any time you put something into the body that's not normal in the body, the body can react to it in a severe way, in an allergic way.

It's when your throat can swell; your face can start to swell; you can have a hard time breathing.

Q. Are you aware of patients experiencing an anaphylactic response when taking Humira?

A. Both products' labels state that anaphylaxis is a potential side effect.

Q. What happens if a patient experiences an anaphylactic response when taking Humira at home?

A. Then, I would imagine, you would hope that there's someone there who can get them to an emergency room or call for an ambulance.

Q. So at least in those instances, it might be a benefit to actually have a healthcare professional or some equipment close by; is that right?

A. That's right. And that's why the requirement for a crash cart.

Q. Now, Mr. Lee also asked you some questions about dermatological use for Remicade.

A. Uh-huh.

Q. And he pointed out that derms do not prefer to do the infusions in their office, correct?

A. They typically aren't as likely to want to do infusions in their office as the rheumatologists or the gastroenterologists.

Q. But that doesn't mean dermatologists don't prescribe Remicade, correct?

A. No. In fact, of the audience that we called on, we estimate that over half of the dermatologists write Remicade. They prescribe it in their patients. They just do not give it in their office.

Q. Then what happens to that patient, once he receives a prescription for Remicade from his dermatologist? What does he do?

A. The dermatologist would refer them to another specialty who does infuse. He could send them to a rheumatologist's office or to a gastroenterologist's office. He could send them to a hospital or any other kind of infusing clinic to get the drug.

Q. Switching gears again, Mr. Lee asked you some questions about Remicade's use with Methotrexate, correct?

A. That's right.

Q. And Centocor doesn't make Methotrexate; is that right?

A. No. Methotrexate is made by a number of other companies. You can buy it generically.

Q. Does Centocor actually sell Remicade together with Methotrexate?

A. No. They are separate products. They are packaged and sold separately by different companies.

Q. And the only -- the only label that Remicade has indicated for use with Remicade is RA, correct?

A. That's correct.

Q. And Remicade is, nonetheless, used quite a bit for RA without Methotrexate, right?

A. Our tracking data suggests about 15 to 20 percent of use is without Methotrexate.

Q. Now, Mr. Lee indicated that Methotrexate is a pretty powerful drug; is that right?

A. That's correct. That's what he said.

Q. And he indicated there can be some issues with taking Methotrexate; is that right?

A. There can be side effects; there can be adverse reactions that occur with Methotrexate.

Q. If that's the case, why would any patient want to take any of these anti-TNF products together with Methotrexate?

A. Because as I -- I think I indicated earlier, clinical trials that have been done with all of these

biologic agents, both with and without Methotrexate, suggest that they're all more effective when given with Methotrexate as compared to when they're given alone. The exception is Remicade, which was never studied as a monotherapy, and that is the reason that Remicade doesn't have the label for monotherapy. It was just never studied that way.

Q. And just to be clear, there's nothing improper about a doctor prescribing Remicade for RA without Methotrexate, correct?

A. No. In fact, I think the physician's judgment would be if the patient has previously tried Methotrexate and it didn't work, there's no ethical reason to continue Methotrexate. Or if the patient were having an adverse reaction or experience on Methotrexate, it would make sense that you would discontinue the drug.

Q. Now, you were also asked some questions about the perceived safety of Remicade.

Do you recall that?

A. I do.

Q. Again, are you aware of any data that actually shows that Remicade is less safe than Humira?

A. Again, I'll go back to my earlier answer to show that in a way that is meaningful. You would

actually have to do a head-to-head study and show that there are difference. And there have been no head-to-head studies conducted between these drugs. The labels, which is what the FDA allows us to say when we talk to doctors and patients about the drugs, all essentially say the same things. The same types of adverse reactions that you see with one are always contained in the labels for the other.

Q. And Mr. Lee seemed to be suggesting that doctors and patients just don't like Remicade because it's unsafe.

Do you recall that?

A. I do recall that.

Q. Is that really the case?

A. It's not the case. And as I said, Remicade has actually been used in more patients than either of the other biologics. I think that would not be the case.

There have been a number of products that have been removed from the market because they were unsafe, like Raptiva and others. And, again, that would be an action that the FDA would take if in any way Remicade was an unsafe drug to give these patients.

Q. In fact, you put up Remicade sales numbers, and those were pretty substantial sales numbers, right?

A. Yes.

Q. That indicates to you that the market actually likes Remicade?

A. Yes. That's the most frequently prescribed biologic. I would say yes.

Q. It has never been pulled off the market by the FDA, right?

A. No. In fact, over -- part of the reason that you see the growth in sales that Mr. Lee pointed to over all of those years is that we went from about three indications, three approved indications when I joined Centocor, the year where we started, to about 15 indications.

So not only have they not pulled it from the market, they have continued to approve new indications year after year.

Q. How many patients have used Remicade since it was launched?

A. It's hard to estimate, but our guess is somewhere around 1.2 million patients.

Q. And in all of those indications that we have listed on our score card, what product is Remicade's primary competitor for those indications?

A. I would say if you look across the board in all the therapeutic areas, Humira clearly is the one

that competes most directly with us in each of the three therapeutic areas.

Q. Thank you.

MR. MASLOWSKI: Nothing further. Pass the witness.

MR. LEE: I have a few questions, Your Honor.

THE COURT: All right.

REDIRECT EXAMINATION

BY MR. LEE:

Q. Mr. Bazemore, you just told your counsel you understood that I was suggesting that Remicade was an unsafe product.

A. He was on -- he was asking in reference -- I think he was asking in reference to a quote. I was just commenting on that.

Q. In fact, you were here for the opening, correct?

A. I was.

Q. And you heard me say that Remicade's a great product; no one wants to take that away from you, correct?

A. Correct.

Q. And no one is trying to, are they?

A. I don't think so.

Q. Right. What I was talking about is Plaintiffs' Exhibit 261, which you showed the jury, at Page 20, about what you were reporting to yourself about safety concerns, correct?

A. That's correct.

Q. And just so the jury's clear, you can't take a single patient, like Mr. Beck here, and put both Remicade and Humira in him to see which one is working better, correct?

A. No. That's true.

Q. That's what you don't want to do, correct?

A. That's correct.

Q. So what you've collected is the best available data absent that, and the documents I went over with you are just what Centocor was saying to itself, correct?

A. That's correct.

MR. LEE: Nothing further. Thank you, Your Honor.

MR. MASLOWSKI: Nothing further, Your Honor.

THE COURT: All right. You may step down.

MR. MASLOWSKI: May the witness be excused, Your Honor?

MR. LEE: Yes, Your Honor.

THE COURT: All right. You're excused. You may step down.

Who will be your next witness?

MR. SAYLES: May it please the Court. At this time, we'd call Dr. Rebecca Hoffman by deposition. This one lasts a minute and 41 seconds.

I'll tell you before we play it, and I will read the agreed-upon introduction, if it please the Court.

Members of the Jury, you will now hear portions of the deposition testimony of Dr. Rebecca Hoffman. Dr. Hoffman received her undergraduate degree in microbiology from the University of Illinois in 1979. She then received her medical degree from Rush Medical College in 1984. She's worked for Abbott since 1998. Until very recently, she served as the Divisional Vice President for Abbott's Immunology Group and was responsible for the clinical development of Humira.

Dr. Hoffman testified at her deposition as a corporate representative on Abbott's behalf on topics related to the research and development of Humira.

(Video playing.)

QUESTION: What do you call the immunologic response that patients can experience when

receiving Humira?

ANSWER: So there's different kinds of immunologic responses that they could have. They could have, say, an allergic reaction to the medication, which would be an immunologic response.

They can also develop antibodies against the Humira, which would be considered an immunologic response. Those are two examples.

QUESTION: But Abbott is not allowed to advertise the allegation that its immunogenicity is better than Remicade's, correct?

ANSWER: That is correct.

QUESTION: And the FDA actually precludes Abbott from making that claim, correct?

ANSWER: I know in the label it states that the different methodologies cannot be compared.

QUESTION: And that label had to be approved by the FDA, correct?

ANSWER: Yes.

QUESTION: Have you done any types of tests at all with respect to Humira's immunogenicity?

ANSWER: So our clinical trials did test immunogenicity in patients that weren't in the trials.

QUESTION: Do you know why Remicade is administered via IV infusion?

ANSWER: No, I don't.

QUESTION: Does the fact that it's a chimeric have anything to do with the fact that it's IV-administered?

MS. MAJOR: Objection.

ANSWER: Not that I know of.

QUESTION: And similarly, the fact that Humira is a human antibody has nothing to do with the fact that it's administered via subcutaneous administration as opposed to IV infusion, correct?

ANSWER: That's correct.

(End of video clip.)

THE COURT: What do we have next, Mr. Sayles?

MR. SAYLES: May it please the Court.

Before we call our damage expert witness, Dr. Gering, I have several stipulations that relate to the issue of damages that I'd like to read at this time.

THE COURT: Okay.

MR. SAYLES: Stipulation No. 12: Abbott's U.S. Humira sales by indication and through April 2009 are reflected in Plaintiffs' Exhibit 109, Plaintiffs' Exhibit 686, and Defendants' Exhibit 895.

13: Abbott's international Humira sales through April 2009 are reflected on Plaintiffs'

Exhibit 116, Plaintiffs' Exhibit 846, Plaintiff's Exhibit 285, Defendants' Exhibit 893, and Defendants' Exhibit 894.

14: Remicade profit and loss statements for the United States are reflected at Plaintiffs' Exhibit 731 and Plaintiffs' Exhibit 841.

15: Centocor profit and loss statements for the United States are reflected at Plaintiffs' Exhibit 842, 843, 844, and Plaintiffs' Exhibit 860.

16: Humira profit and loss statements for the United States are reflected at Plaintiffs' Exhibit 111, Plaintiffs' Exhibit 690, Plaintiffs' Exhibit 112, Plaintiffs' Exhibit 113, Plaintiffs' Exhibit 114, Plaintiffs' Exhibit 110, and Plaintiffs' Exhibit 847.

17: Humira profit and loss statements for outside the United States are reflected at Plaintiffs' Exhibit 674, Plaintiffs' Exhibit 675, and Plaintiffs' Exhibit 673.

At this time, we would call Dr. Richard Gering.

THE COURT: All right.

COURTROOM DEPUTY: Raise your right hand, please.

(Witness sworn.)

RICHARD GERING, Ph.D., PLAINTIFFS' WITNESS, SWORN

DIRECT EXAMINATION

BY MR. SAYLES:

Q. Tell the ladies and gentlemen of the jury your name, please.

A. My name is Richard Gering.

Q. And tell us a little bit about yourself.

A. I was born in Capetown, South Africa. I met a girl from Philadelphia, and we now live in Philadelphia and have two boys, a 16-year-old and a 14-year-old.

Q. Have you been retained on behalf of the Plaintiffs to analyze the available data and come here to express opinions on the economic damages that have been sustained in this case?

A. I have.

Q. How are you currently employed?

A. I'm a principal at Parente Randolph, which is an accounting and consulting firm.

Q. Can you explain to the jury what your work is, what you do?

A. I quantify economic damages in cases like this, and I do economic analysis where I do strategic and pricing analyses.

For example, when a competitor is introducing a new product, I would do an economic analysis of that.

Q. Do you have specific experience in quantifying damages in patent cases, like the one now in trial?

A. I do.

Q. Approximately how many other patent cases have you been involved in where you've analyzed data?

A. More than a hundred.

Q. Have you been accepted in federal court previously to testify as an expert and give opinions on economic damages?

A. I have.

Q. Have you been accepted in a Texas federal court on the issue of economic damages?

A. I have, in Lufkin, Texas.

Q. Would you explain your educational background to the jury, please?

A. I have a Bachelor of Commerce from the University of Natal in South Africa. And then I have a Master's and a Ph.D. from the University of Maryland. And I also have a CLP, which is a certified licensing professional designation, and that's given out by the Licensing Executive Society.

Q. Have you held previous positions where you did work similar to the type of work that was required to ready yourself to give opinions in this case?

A. Yes. While I was getting my Ph.D., I did some

economic modeling teaching while I was getting my Ph.D. Then I worked at an economic consulting firm. And then in 1992, I started working at PriceWaterhouseCoopers, and I did the same kind of work as I'm doing today. And I moved to Parente in 2002.

Q. Do you currently teach?

A. I do. I'm an adjunct lecturer at the Villanova University Law School, which is just outside of Philadelphia, and I teach economic damages there, including patent damages, to those students.

MR. SAYLES: I'd like to show the jury Plaintiffs' Exhibit 466, which is in evidence, Your Honor.

Q. (By Mr. Sayles) And is this your CV or your resume?

A. Yes, it is.

Q. And does it more fully describe some of your background and the credentials that you hold?

A. It does.

Q. I want to turn to the lectures and presentations and the publications and presentations. There's quite a list there.

Have you given lectures to professional societies and professional groups?

A. Yes, I have, to intellectual property law

groups, as well as to the American Institute of Certified Public Accountants, to their national conference.

Q. And have you written papers and articles for publication?

A. Yes. I've written on both quantifying reasonable royalty damages and lost profit damages in patent cases and in other kinds of cases.

Q. Have you written on the very subjects that you've been asked to evaluate in this case and express opinions to this jury about?

A. I have.

Q. I'm going to ask you some questions about your opinions on damages, Dr. Gering, in a few minutes, and whenever you're expressing your opinion, I'm going to ask you to confine yourself to reasonable probability and not guesswork or speculation.

Will you do that?

A. I will.

Q. All right. Let's focus specifically on the work you did for this case. I want to speed things along, because we respect everyone's time, but I'd like the jury to know if you did your homework.

Can you tell us what you did to prepare for this case, please?

A. I can. I looked at Abbott and Centocor strategic and marketing plans, very similar to the ones that were just shown up on the screen the last hour; surveys and studies of opinions and perceptions by doctors, in some cases, by payors and some cases by customers.

I looked at financial sales data, profitability data, cost data. I also met with and interviewed 17 different Centocor employees in the manufacturing, licensing, medical affairs, competitive analysis, market research.

I reviewed depositions and expert reports from the other side.

I had access to a database of over 3 million documents. I did not look at 3 million documents. I looked at probably 2 or 300,000 different documents myself and my team that were related to the areas that my opinion is related to.

Q. Were you permitted access to confidential documents of both Abbott and Centocor as permitted by the Court's order regarding confidentiality in this case?

A. Yes. So, for example, I could -- I could look at the market perceptions or research both by Abbott, as well as Centocor, and I could account for both of that

in my analysis.

Q. Did you have any assistance in reviewing all of this material and getting ready for your testimony here today?

A. I did. I worked -- three people worked under my direction on this project.

Q. Is your pay or your compensation in any way contingent on the outcome of this case?

A. No, it's not.

Q. Is it typical in a case like this for you and experts in your field to make certain assumptions?

A. Yes, it is.

Q. And did you make some assumptions in this case for purposes of your analysis?

A. Yes, I did. I assumed that sales of Humira were infringing Centocor's '775 patent.

I was also aware that an arbitrator had ruled with respect to certain sales of Humira that are used with Methotrexate and that the arbitrator had quantified those percentages, and I had -- and I took those percentages, and I accounted for them in my calculations.

Q. Before we go into the details of your opinions, let's get them out.

Have you performed a professional opinion as

to the amount of damages suffered by the Plaintiffs in this case as a result of infringing Humira?

A. Yes, I have.

MR. SAYLES: And could we see Slide 2?

Q. (By Mr. Sayles) And I'll ask you if this summarizes the damages that you have determined in this case?

A. Yes, it does. And it's -- and there are two different types of damages.

The first one is damages in the form of what's called lost profits, and that number is 1,168,466,000.

And then on those sales that are not in the lost profits calculation, I quantified what's called a reasonable royalty, and those numbers are 1,008,256,000 so that the total damages that I have quantified are 2,176,722,000.

Q. Dr. Gering, you've mentioned two different categories of damages here. Are these two separate categories?

A. Yes, they are.

Q. Is there any double dipping here?

A. No, there is not.

Q. And the first that you mentioned is lost profits. Can you please describe to the jury what you mean by lost profits?

A. Yes. So, again, I've assumed that Humira infringes, and I'm saying that if there was no infringing Humira on the market, Centocor would have more -- have made more sales of Remicade -- sold more sales of Remicade.

And I've quantified that number, and then I've subtracted out the cost of making those sales to arrive at what's called the profits that Centocor would have made on those additional sales had infringing Humira not been on the market.

Q. And the second category of damages that you mentioned that we have here is a reasonable royalty. Before we dig into this, just tell us generally, what is a reasonable royalty?

A. So not -- not all of the infringing sales in my analysis would have resulted in additional sales of Remicade. Only about one in five.

And so the other infringing sales of Humira, I quantify reasonable royalty. And what that is, is if Abbott and Centocor had sat down and had a negotiation, Abbott would have paid a license fee to Centocor so that they could make and sell Humira and use the '775 patent and that technology.

And that -- that's called the reasonable royalty analysis.

Q. In your analysis here, is July the 4th of 2006 an important date?

A. Yes, it is. July --

Q. What's the significance?

A. July 4th, 2006, that is the date that the patent was issued, and so that is the starting date of all my damages calculations. I don't calculate any damages before July 2006.

Q. Now, before we go through your lost profits analysis in more detail, did you prepare a slide that quantifies Abbott's sales of Humira since July of 2006?

A. Yes, I did.

Q. And can we take a look at that, please.

A. Yes.

Q. Would you explain this.

A. I will.

If you look at the title, it says the total sales of Humira, and that's worldwide, from July '06 through June of '09 are $11.2 billion. And I've broken that up into three major groups.

The first group is the yellow slice, which is $2.9 billion of Humira sales, and those are sales of Humira that are used with Methotrexate, sometimes called the co-administered sales.

Those are the sales that are a result of the

arbitrator's ruling. The arbitrator gave us various percentages, and using those percentages, I've quantified the sales and removed the sales.

So you can see in the box that there are no damages associated with those $2.9 billion in sales.

In the next smaller wedge is 1.6 billion in the lost profit analysis. And that's where my analysis shows that in my opinion, if infringing Humira was not on the market, Remicade would have made those sales. And Remicade, in my opinion, is, therefore, titled to the profits it lost on those sales.

And then the last section, the $6.7 billion, those are the remaining infringing Humira sales where I'm saying Remicade would have not made additional sales. And those would be subject to this negotiation where Abbott would pay a license fee to Remicade.

Q. No double counting between lost profits and reasonable royalty?

A. Correct.

Q. And you took out the arbitrator's award?

A. Correct.

Q. All right. Let's move to lost profits, and let's talk about the lost profits analysis.

Can you explain to this jury how you calculated lost profits in this case?

A. I can. I went through an analysis that really is sort of a four-prong test. It's sometimes called the Panduit case after a case of that same name.

And it goes through and basically asks and answers four questions that one performs in order to determine and quantify the lost profits amount.

And I have a slide that walks through those questions.

Q. All right. And before we get there, did you consider the market in which these products compete?

A. I did. I looked at the biologic market in the United States where these products compete, and I summarized -- I think this morning you've seen a lot of information on the biologic market, but I have a brief summary just to show some of the sales information and who the major products are in that market.

Q. Is this the summary of that?

A. Yes, it is. And so --

Q. Would you explain it?

A. -- this summarizes sales in the biologics market. It looks like at 2006, the market's about $8 billion in total sales, and it grows every year. In 2008, it's over 12 billion, and the expectation in 2009 is that it will be over 14 billion.

And you can see that there are three products

that comprise over 95 percent in the early years, and at the end of the time period, about 95 percent of the market. It's Humira, it's Remicade, and it's Enbrel.

You can see that they're color-coded. There's also a little purple sliver at the top, and those are the other products in the market. There are about four or five products in '06. I believe there now may be eight products in '08 and '09 that comprise that purple sliver at the top.

So, again, the market is characterized by these three products: Humira, Enbrel, and Remicade.

Q. Are there specific factors that you look at to analyze lost profits in a case such as this one?

A. Yes, there are. As I said, you go through the four-prong Panduit test, and I did that.

In my opinion --

Q. Can you explain -- can you explain those?

A. I'll give the questions in more of a form of the answer.

Q. I'd like you to explain those factors that you went through and considered in connection with the lost profits analysis so the jury has that background.

A. Okay. So the first issue I looked at is demand. And in my opinion, there is demand for the products covered by the patent. In this case, that

would be Humira. And the patent is the '775 patent. So there is demand for Humira that uses the '775 patent.

The second thing I looked at is called non-infringing alternatives. One has to look at what the world would look like if there was no infringing Humira sales.

And, in my opinion, one can look at that market and one can determine what Centocor's market share would be in the market after removing the infringing sales.

And I say I do that in each indication. Because as you've heard, there's rheumatology, gastroenterology, and dermatology, and within that, there are a number of other diseases.

And they're all slightly different. The analysis is conceptually the same, but the numbers in that are slightly different. So you have to look at it by indication.

The third thing I looked at and reached an opinion on is if Centocor would have been able to sell more Remicade, which I find, did they have the ability to make more Remicade, and did they have ability to sell more Remicade? Did they have the manufacturing and marketing capacity?

And, again, I looked at various documents,

spoke to various people, and I found that they did.

And then the last part of the test is, can you do the quantification? Can you calculate the profits that Centocor would have made on those Remicade sales that it should have made without infringing Humira.

Q. And with respect to those factors, would you explain the basis of your opinion, please.

A. Yes. I looked at various information. I spoke to various people. And then what I did was, I worked through each individual fact in order to quantify my lost profits.

So the first thing I looked at, for example, was, was there demand? And in my opinion, there was demand.

Q. All right. Would you take a look at the Humira sales in your damage analysis and explain to the ladies and gentlemen of the jury how this ties in?

A. This shows sales of Humira, but this time it shows it by timeframe.

If you look from 2003 through half of 2006, you can see that sales are growing. They're all in a white box, because, again, those are before July 2006, so they're not in the damage period.

The green bars are the sales of Humira that are in the damages period.

And then the little blue bars at the top, those are the sales of Humira when they are used with Methotrexate, which, again, according to the arbitrator ruling, I've quantified, accounted for, and taken them out.

So what you can see is there clearly is demand for Humira. That's a tremendous number of sales. In 2008, for example, 4 1/2 dollars in sales. Those sales are growing.

And again, my assumption is that Humira is infringing, and therefore, that it uses Centocor's '775 patent. So there is -- there is demand.

Q. And did you review Remicade and Humira to determine if they compete in the same market?

A. I did.

Q. And what is your opinion in that regard?

A. In my opinion, they do -- they do compete in the same market.

Again, I looked at physician preferences. I looked at market share information. I looked at various studies. We've seen some of the studies this morning. I've looked at the same studies or the same type of studies, maybe different versions of them. Africa has very similar studies.

I also spoke to various people in marketing.

I spoke to Mr. Bazemore, for example, and various people that report to him, and then to medical affairs.

And by analyzing that, I was able to determine that they are perceived similarly. There are some differences, but they're perceived similarly. And once Humira came on the market, it did compete with and take sales from Remicade.

Q. And based on your review of the documents available from both Abbott and Centocor, do Humira and Remicade become viewed as comparable by doctors and patients?

A. Yes.

Q. And if you would, tell the ladies and gentlemen of the jury, what leads you to conclude that these two products do compete with each other in the same market?

A. Again, it's the type of information I looked at -- and I have some examples of that information -- that, in my opinion, does lead me to conclude.

So this is a -- this is a document from Abbott. It's a similar type of document -- you've seen earlier ones -- from Centocor. It's an October '07 document. It's from Scott Luce, who's the Vice President of Abbott Immunology.

And it clearly says at the bottom, In

gastroenterology, which is mainly Crohn's disease, we've talked about, we currently have one competitor, Remicade. As you can see, we have been taking share from Remicade.

If you look at the chart, you see that Remicade's share was about 95, 97 percent, and then it starts dipping down, and the Abbott share of Humira goes up. And that's around early '07, which is when Humira gets approval in the gastroenterology field for Crohn's disease.

So clearly, sales, as reflected by market share, decreased and went from -- patient share went from Remicade to Humira.

Now, in truth, both companies are increasing sales over that time period, but the distribution in the market is moving from Remicade to Humira.

So that's one example. I looked at also other examples where Remicade was compared to Humira by both companies.

So the first bullet point at the top is an Abbott marketing document that says Humira, Enbrel, and Remicade -- again, those are the big three -- are ranked similarly with respect to rheum perception -- and rheum perception would be doctors, rheumatologists -- of overall product performance.

So there are many ways that you can look at -- or that doctors look at how products are used and performed and why they use it. This is a top-line view of the overall product performance. They ranked the three very similarly.

The second document is a -- is a Centocor document, and I believe that we just saw that one recently or another page of it, and it says here, "Remicade, Enbrel, and Humira continue to be perceived as similar on most efficacy attributes."

And, again, this is a study of physicians' perceptions on what they think about the products.

Let me back up to No. 7, and I want to ask you just a couple of questions about this.

First of all, there's an ABT number here, and that indicates that this is an Abbott document; is that right?

A. That is correct.

Q. And although we've got the logo down here -- that's been added on -- this is one of the confidential documents to which you were given access.

A. Yes. And if you look on the actual slide, I guess sort of in the bottom right, you see the A and Abbott, which Abbott typically has on its...

Q. And these underlined words in red, the -- not

the underlining, but the words are on the document of Abbott; is that right?

A. Correct. They're often called speaker notes. A person presents a slide, and then they write at the bottom of the slide notes to help themselves give a presentation to their audience.

So, obviously, Mr. Luce or somebody on his staff present -- wrote those notes in in order to explain the slide.

Q. All right. This is an example. Did you see very many documents internally from Abbott that indicated that their product, Humira, competed with Remicade?

A. Absolutely.

Q. All right. Let's go to No. 9. Is this another example of an Abbott document about its competition with Remicade?

A. Yes. And this is a document from January of '08. Again, it's focused on Crohn's, and it's part of a slide deck that talks about -- this part is talking about looking ahead. What's going to happen in 2008, what Abbott wants to happen, what it expects to happen. And it wants to grow its market share, and it wants to do it in three ways.

So if you look on the right-hand side, there

are three bullet points, and if you start at the bottom bullet point, it says maintain current patient base. So Abbott is saying, in order to grow our share, the first thing we need to do is maintain current patient base. And that's sort of that bottom line where the -- where the -- let me try with this. So that line is to maintain current patient base.

The next thing, it says, take share from Remicade, and that's to get the chart up to that point. And the last thing it says, expand the biologic market. You can't see it very clearly, but there's another line that sort of takes you up to about there.

And so what they're saying is, we want to grow the market, we want to grow our share in the market, we want to grow our sales, and we're going to do it by keeping our patients, by taking share from Remicade, and by expanding the market.

And expanding the market typically is both growing the market, but it's also taking all those Remicade failures, people who have tried Remicade and Remicade is not working for whatever reason. So that's part of expanding the market.

And if you look at the sales data, like I did, at the end of 2008, they did achieve their goal, which they say in the starburst that they thought was totally

achievable, and indeed, it was.

Q. All right. If you would now, take a look at Slide No. 10 and tell us what Plaintiffs' Exhibit 666, another Abbott document, shows.

And by the way, the arrows are our addition to the document.

A. That is correct. I marked this slide with Enbrel, Remicade, and Humira, which -- because it's not that easy to -- I didn't find it that easy to read the slide, so that's why I did it.

And Abbott's point in the slide is, it's looking at Humira total U.S. market share, so across all the indications, all the disease categories. And it's saying that Humira is advancing its position amongst the entrenched competition. That would be Enbrel and Remicade.

And you can fairly clearly see that certainly from '04, '05, the Remicade line is going down, and it looks like the Humira line is going up by a similar amount. Enbrel is also coming down slightly.

So that's also, in my mind, evidence not only that people thought that they were similar but that they actually competed. Because once chimera came in the market, you can see that share moved, sales moved, new patients moved from Remicade to Humira.

Q. Abbott document?

A. Yes.

Q. Showing that they considered Remicade one of the entrenched competition?

A. Correct.

Q. Now, after you determined that Humira and Remicade competed in the same market, what did you do?

A. So I have all this information that they do compete. So now I have to quantify that information. I have to quantify what the sales of Remicade would be in a world where I have to take out the infringing Humira.

So how many -- how many of those Humira sales would Remicade have achieved?

And again, I have to do that by indication and by year. And I did that by looking at, again, data and share data and sales data and perception data from both Abbott and Centocor and combining that information.

Q. Would you take RA as an example and walk the ladies and gentlemen of the jury through how you went about adjusting the market share analysis.

A. I will.

So the slide at the top -- let me give you the conclusion, and then I'll walk you through how I did it, because it's fairly complicated.

I'm saying that Remicade's adjusted market

share of Humira in the United States for RA in 2008 is 39 percent.

So what I mean is, if you took out infringing RA, then 39 out of every hundred patients that would have gone to Humira instead would have gone to Remicade. And the other patients, the other 61 patients, would have gone somewhere else. They would have not used Remicade.

So I started with the total sales of Humira in RA in the United States in 2008, and the first thing is, I removed the Humira sales that are used with Methotrexate.

Remember, that's the way that the arbitrator told us how to calculate those numbers. So they're excluded. They're not in any of the damages calculations.

The third thing you have to do is you have to understand how the patient got to Humira. We've heard first line and second line and biologically naive, and that's what I'm addressing here.

Saying some of those patients --

THE WITNESS: If you would just back one up.

A. Some of these patients had tried Remicade and it had failed, 11 percent. Some of them had tried

Enbrel and had failed. And some of them, 69 percent, Humira was the very first biologic that they tried. So you have to understand that.

Then if you go one step further -- so if a patient has tried Remicade and it hasn't worked for whatever reason, I'm saying that even if you remove infringing Humira, that doctor would not put that patient back on to Remicade. It's tried; it's failed. So Remicade gets zero of that share.

If they've tried Enbrel, whatever reason the doctor's taken the patient off Enbrel, if there's no bringing Humira on the market, it's not going to go back to Enbrel for the same reasons. It's tried -- they've tried Enbrel; it's failed. And I'm saying that Remicade gets about 90 percent of those sales.

There are some other products in the market, as we saw, less than 5 percent, so Remicade gets about 90 percent of that.

The third group is the biologically naive. So they -- Humira was their very first choice. There is no infringing Humira. They can now choose Enbrel, they can now choose Remicade, or they can choose some of those other products that are smaller percentages.

If you look at the data, the vast majority of those patients would go to Enbrel. That's what happened

in the real world. That's what would happen if you take out infringing Humira.

And so Remicade only gets 30 percent of those biologically naive, and 70 percent go to other places.

So when you put it all together, you have zero; you have 90 percent of 20, which is 18; you have 30 percent of 69, which is 21; and you add it together.

And what I'm saying is the adjusted market share, in other words, Remicade's share of the market in RA in the U.S., after extracting the infringing Humira and after accounting for the arbitrator's ruling, is 39 percent.

Q. (By Mr. Sayles) Now, Dr. Gering, let me be clear about something. You understand that in this case, there is no effort being sought to remove Humira from the market in actual fact.

A. That's correct. This is a -- what a damages person does is an analysis to say, let's assume that there is no infringing Humira. What would doctors have prescribed and what would patients have used?

In the real world, obviously, there is Humira. And in the real world, nobody is seeking to take Humira off the market. This is -- this is solely for the purposes of calculating what the world would have looked like had Humira not been there infringing.

So it's not what is actually going on in the sense that Humira is actually being sold today.

Q. It's just necessary for a proper analysis of lost profits.

A. Correct.

Q. Now, just a couple of questions about this, and then we'll move on to the summary.

Under previously Remicade and the reallocation, you have Remicade share zero.

A. I do.

Q. Why is that?

A. Again, that's because for that segment of the RA market, a patient had already tried Remicade before coming to Humira, and for whatever reason, the doctor had taken the patient off Remicade.

Then my understanding is, once you've tried one of these products and you've been -- and they've been taken -- you've been taken off that product, doctors typically do not put you back on the product. You try something else.

Q. Did you go through an analysis of the market share for each indication? We've just talked about RA.

A. I did. And the next slide will show those numbers.

Q. Well, let's go to that. But can we -- can we

get you to verify that, in fact, you went through a detailed analysis, and this is a summary of each of the additional areas or indications where these drugs are utilized.

A. Absolutely. I did the same analysis -- for example, in RA, we walked through 2008; the same analysis for RA for '07 and '06; and then I did the exact same analysis for the other four indications, AS, PsA, PS, and CD.

And you can see that the numbers are different. There's some slight differences in which products are on the market. There's slight differences in how they're perceived, how they're used, how they're prescribed, what their actual sales are.

So, for example, we know in PS, it is a dermatological condition, and we know that Remicade does not compete as effectively with dermatologists. Some dermatologists have a reticence to use it, their perceptions about maybe its safety or their perceptions maybe about wanting to use an IV product.

And so in '08, I'm only asking for 11 percent of the infringing Humira sales in my lost profits.

And if you look at Crohn's disease, for example, where there are much fewer competitors, my market share number is much higher. It's 69 percent,

for example, in 2008.

So the analysis is inherently the same; the types of documents were the same; but the numbers are different. And that's why you have to do the analysis by indication.

Q. And you've done that.

A. I did.

Q. All right. And if we do a lost profits calculation, again taking rheumatoid arthritis as the example, can you explain to the jury how you did that?

A. Yes, I can.

So this is the last part of the four-pronged Panduit test to actually calculate lost profits. I also looked, obviously, at the manufacturing and the marketing ability.

This is one of the few areas that both experts on both sides agreed upon, that Centocor did have the ability to make the property and did have the ability to sell the products. There was no real dispute there. I did -- obviously, did the analysis, but there was no dispute there.

So what we do here is we start off with the infringing sales of Humira in RA. We then have to understand, but for the infringement, how many of those sales would Remicade have made. And so that's the

market share analysis that we just did.

When you -- after you do that, that will determine how many sales Remicade would have made; in other words, what they lost due to the infringement. And then the last step is, you have to turn that revenue number, that sales number into a profit number. So you have to look at the profitability of the product. You have to take out the cost of making it, the cost of selling it.

Centocor pays some monies to other companies and other institutions to use various other parts of their intellectual property, so you have to do an analysis to see what are the profits.

So that shows conceptually what I did, and if you advance the slide, that puts the numbers in place.

So what I'm saying is, there are 1,991,000,000 sales in the United States of Humira in the Remicade indication.

Now, that number is after taking out, already removing, $1-1/2 billion of sales in the United States of Remicade with Methotrexate in the RA market.

I'm saying, if infringing Humira was not on the market, Remicade would have made 791 million of those almost 2 billion in sales. And the profits that they would have made on those sales would have been

582,946,000, so that would be for RA.

Q. All right. And did you do a similar analysis for each indication?

A. I did.

Q. And I noticed that the incremental profit margin here is different for each year. Tell the ladies and gentlemen of the jury why these numbers are different from year to year.

A. Well, the analysis is based on the actual profit and loss statements for -- it's my watch; I'm going to try to stop it -- for Remicade. And I believe that Mr. Sayles read in the documents that are related to that profit and loss statement.

So I looked at them specifically by year. They're slightly different every year. I spoke to the Chief Financial Officer of Centocor, and I spoke to three people that worked with that -- with the Chief Financial Officer about various aspects, for example, the cost of making the product, promotional costs of the product, other licensing revenue that they pay on the product.

So it's different by every year. The analysis, again, is similar.

Q. All right. Let me ask you, now, is this number over on the right-hand corner the number for lost

profits in rheumatoid arthritis?

A. Yes, it is.

Q. Let's take a look at No. 14. Did you go through a similar analysis that you just told the jury about in each and every indication?

A. I did. And as you saw before, the market share numbers are slightly different, the sales numbers -- Humira sales are absolutely different. They start at slightly different time periods whenever Humira got on the market, but it's the same analysis.

So when you add up the lost profits in all the different indications, it's 1,168,466,000. So that's the lost profits in the United States by indication.

Q. And is that your professional opinion of the lost profits that have been sustained in this case by the Plaintiffs?

A. It is.

Q. Now, let's -- let's move to the next slide, and I'd like you to explain to the jury what this lost profits number represents in terms of the overall sales.

A. Well, again, we've seen this slide before.

What we've been talking about is the $1.6 billion in sales, additional sales, that Remicade would have made in a world in which there was no infringing Humira, according to my analysis. And we've quantified

the profits on those sales of 1,168,000,000.

So, again, that's just -- that's that segment. And then the next area to address is the reasonable royalty on the remaining sales that, again, I've assumed to infringe and that are subject to my analysis.

Q. All right.

THE COURT: I think we'll move to the reasonable royalty after lunch.

MR. SAYLES: All right. Very well.

THE COURT: Ladies and Gentlemen, we'll take a lunch break until 1:15. Be ready to come back in the courtroom at 1:15.

Remember my instructions about not discussing the case among yourselves. Have a nice lunch, and I'll see you back here.

COURT SECURITY OFFICER: All rise.

(Jury out.)

THE COURT: I can remember when we used to get excited when the damage figure was a million, Mr. Beck.

MR. BECK: It's the B that's getting to me, Your Honor.

THE COURT: I understand.

(Recess.)

* * * * *

CERTIFICATION

I HEREBY CERTIFY that the foregoing is a true and correct transcript from the stenographic notes of the proceedings in the above-entitled matter to the best of my ability.

/s/_____ _____
SUSAN SIMMONS, CSR Date
Official Court Reporter
State of Texas No.: 267
Expiration Date: 12/31/10

/s/_____ _____
JUDITH WERLINGER, CSR Date
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